

1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF ARIZONA
3

4
5 In Re: Bard IVC Filters) MD-15-02641-PHX-DGC
6 Products Liability Litigation)
7) Phoenix, Arizona
8) May 25, 2018
9)
10 Doris Jones, an individual,) 1:00 p.m.
11)
12) Plaintiff,)
13)
14) vs.) CV 16-00782-PHX-DGC
15)
16)
17 C.R. Bard, Inc., a New)
18 Jersey corporation; and Bard)
19 Peripheral Vascular, Inc., an)
20 Arizona corporation,)
21)
22) Defendants.)
23)
24)
25)

14 BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

15 REPORTER'S TRANSCRIPT OF PROCEEDINGS

16 (Jury Trial - Day 8 - P.M. Session)
17 (Pages 1755 through 1865, inclusive.)
18
19
20

21 Official Court Reporter:
22 Laurie A. Adams, RMR, CRR
23 Sandra Day O'Connor U.S. Courthouse, Suite 312
24 401 West Washington Street, Spc 43
25 Phoenix, Arizona 85003-2151
(602) 322-7256

Proceedings Reported by Stenographic Court Reporter
Transcript Prepared by Computer-Aided Transcription

1 APPEARANCES:

2 For the Plaintiff:

3 GALLAGHER & KENNEDY PA

4 By: Mark S. O'Connor, Esq.

5 By: Paul L. Stoller, Esq.

6 By: Shannon L. Clark, Esq.

7 By: C. Lincoln Combs, Esq.

2575 East Camelback Road, Suite 1100

Phoenix, Arizona 85016

Add Mr. Mankoff**

8 LOPEZ MCHUGH LLP

9 BY: Ramon Rossi Lopez, Esq.

10 100 Bayview Circle, Suite 5600

11 Newport Beach, California 92660

12 For the Defendants:

13 NELSON MULLINS RILEY & SCARBOROUGH LLP

14 By: Richard B. North, Jr., Esq.

15 By: Elizabeth C. Helm, Esq.

16 By: James F. Rogers, Esq.

17 201 17th Street NW, Suite 1700

18 Atlanta, Georgia 30363

19 WITNESS:

DIRECTCROSSREDIRECTRECROSS

20 MONI STEIN, M.D.

21 By Mr. Combs

1757

22 By Mr. Rogers

1770

23 PAUL BRIANT

24 By Mr. North

1773

1834

25 By Mr. Stoller

1816

JOHN DEFORD

By Video Deposition

1836

MARK WILSON

By Video Deposition

1837

INDEX OF EXHIBITSEXHIBIT

1031

DeFord Deposition Exhibit 283

RECEIVED

1836

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Stein-Cross

P R O C E E D I N G S

THE COURT: You may continue, Mr. Combs.

MR. COMBS: Thank you, Your Honor.

MONI STEIN,

called as a witness herein, having been previously sworn, was
examined and testified as follows:

CROSS-EXAMINATION

BY MR. COMBS:

Q. Good afternoon, Dr. Stein. My name is Lincoln Combs.

Where do you currently reside?

A. Columbus, Ohio.

Q. Columbus is beautiful this time of year, as I know and I
know you know. And what I'd like to do today to get you back
there as soon as possible is just answer a series of yes or no
questions. And that way if you could answer them yes or no, or
say I can't answer that yes or no, that will move things along.
Hopefully that's the last non yes or no question I ask you.

Is that okay, Doctor?

A. Not every question can be answered yes or no, so I will
try. But I can't promise.

Q. Understood. And if you can't answer it yes or no, just
tell us and I will try to re-ask the question or move on,
whatever we need to do.

And I want to start, Doctor, with a few simple
propositions that I hope we can agree on. Can you agree with

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Stein-Cross

1 me that when a manufacturer is aware that its product is not
2 performing consistent with its own safety goals and thresholds
3 it should take the product off the market?

4 A. There's no yes or no.

5 Q. You can't answer yes or no?

01:02PM

6 A. No yes or no.

7 MR. COMBS: Gay, could you pull up Page 137 of --
8 there we go. Starting on Line 22, we're going to go into the
9 next page.

10 BY MR. COMBS:

01:02PM

11 Q. In your deposition you were asked: Do you agree, sir, that
12 when a manufacturer is aware that a product is not performing
13 consistent with its own safety goals and thresholds it cannot
14 ignore that fact?

15 And your answer there at Line 6, after some
16 objections, was: They should take the product off the market.
17 Do you see that? That's how you answered in your July 31st
18 deposition.

01:02PM

19 A. My answer was longer than that and you just picked out a
20 small portion.

01:03PM

21 Q. Did I read from your deposition correctly?

22 A. Yes, you did.

23 Q. Let me try again with another one. And you would agree
24 with me, hopefully you can agree with me, that if a company had
25 bad information of bad performance and serious safety concerns,

01:03PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Stein-Cross~~

1 bringing a product to the market would be outrageous. Did you
2 agree with that statement?

3 A. The statement was a lot longer, but the way you took it out
4 of there, I said that.

5 Q. And finally, you would agree with me that any measurable
6 migration of an IVC filter is considered clinically
7 significant, correct?

01:03PM

8 A. No.

9 MR. COMBS: Gay, if you could pull up Page 160 of Dr.
10 Stein's deposition. And we're going to go to Line 17 through
11 22.

01:03PM

12 BY MR. COMBS:

13 Q. You were asked in your deposition: As you sit here now can
14 you tell us what is the distance that is utilized to define
15 migration by the SIR and ACR? You responded: I can't recall
16 the exact number. I think any migration is considered
17 significant, any measurable migration.

01:04PM

18 Did I read that from your deposition correctly?

19 A. You omitted --

20 Q. Yes or no, please.

01:04PM

21 A. -- clinical.

22 Q. Yes or no please, Doctor.

23 A. I can't answer yes or no.

24 Q. Did I read correctly from your deposition? That's the
25 question.

01:04PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Stein-Cross

1 A. But when you asked the question --

2 Q. Yes or no, please, Doctor.

3 A. -- the word clinical.

4 MR. COMBS: Your Honor, I would instruct you to have
5 the witness answer yes or no.

01:04PM

6 THE COURT: Hold on just a minute.

7 The attorneys on the other side can ask you to explain
8 if they deem it important. For now, if you can answer yes or
9 no, do so. If you can't, just say I can't answer that yes or
10 no.

01:04PM

11 THE WITNESS: I can't answer that yes or no.

12 BY MR. COMBS:

13 Q. You can't answer yes or no whether I read from your
14 deposition correctly?

15 A. Well, you read from the deposition correctly but there was
16 another issue.

01:04PM

17 Q. That's my question.

18 A. Okay. Yes.

19 Q. And Doctor, you did two reports for this case, correct?

20 A. Yes.

01:05PM

21 Q. One on Bard filters generally and one addressing Mrs. Jones
22 and her Eclipse Filter specifically?

23 A. Yes.

24 Q. Let's take a look at your general deposition.

25 MR. COMBS: Exhibit 2465, please, Gay.

01:05PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Stein-Cross

1 BY MR. COMBS:

2 Q. Starting on the first page, this is your general report for
3 this case, correct?

4 A. Yes.

5 Q. And you spent a good chunk of this report discussing the
6 medical literature on Bard IVC filters, correct?

7 A. Yes.

8 Q. And there are quite a few articles out there on Bard's IVC
9 filters, correct?

10 A. Yes.

11 MR. COMBS: Let's go to Page 6, if you could, Gay.

12 BY MR. COMBS:

13 Q. In the middle section there, middle paragraph, you talked
14 about the Binkert study?

15 A. Yes.

16 Q. The Binkert Study is also known as the EVEREST study?

17 A. Yes.

18 Q. That was a study funded by Bard?

19 A. Yes.

20 Q. And the EVEREST study looked at G2 Filters explanted from
21 patients after an average of 140 days. Is that correct?

22 A. Yes.

23 Q. And it found that -- I'm quoting your report here -- caudal
24 migration was seen in 12 percent of filters. That's what you
25 said in your report, correct?

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Stein-Cross

1 A. Yes.

2 MR. COMBS: Your Honor, could I use the ELMO as well?

3 THE COURT: Yes.

4 BY MR. COMBS:

5 Q. And in your report you continued: Filter fracture was seen 01:07PM

6 -- was observed in 1 out of 85, 1.2 percent; filter tilt of

7 more than 15 degrees in 15 out of 85, 18 percent.

8 Did I read that correctly?

9 A. Yeah,

10 MR. COMBS: May I publish this to the jury, Your 01:07PM

11 Honor?

12 THE COURT: Publish what?

13 MR. COMBS: The ELMO.

14 THE COURT: You mean what you have written?

15 MR. COMBS: Yes. 01:08PM

16 THE COURT: Publish that? Any objection?

17 MR. ROGERS: None, Your Honor.

18 THE COURT: You may.

19 MR. COMBS: Thank you.

20 BY MR. COMBS: 01:08PM

21 Q. And I next want to turn to the VJ study which you talked

22 about on the bottom of Page 7 and into Page 8 of your report.

23 And you mentioned the VJ article and you said VJ, et al.,

24 reviewed retrospectively the charts of 548 patients who

25 received Recovery G2 or G2 Express Filters between 2004 to 2010 01:08PM

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Stein-Cross—

1 who came for filter retrieval. 63 fractures were reported for
2 a fracture rate of 12 percent. Excluding minimal foot process
3 fractures, the fracture rate dropped to 6 percent. The average
4 dwell time for fractured filters was 692 days.

5 Did I read correctly from your report?

01:08PM

6 A. I'm not seeing the report, but I think you did.

7 Q. And 692 days is about two years, correct?

8 Is that yes?

9 A. Yes.

10 Q. And then I want to go to the section of your report where
11 you talked about the An study, A-N.

01:09PM

12 MR. ROGERS: Your Honor, may I interrupt for a moment?
13 The witness can't see the report. He either needs a copy on
14 the screen or in his hand.

15 THE COURT: I agree. If you are asking him if you are
16 reading it correctly, he needs to have the report.

01:09PM

17 MR. COMBS: That's fine, Your Honor.

18 Can we switch back to his report, Gay, please, and
19 Traci? Thank you. That's fair. I apologize.

20 BY MR. COMBS:

01:10PM

21 Q. Let's go to Page 7. There we go. Talk about the An Study.
22 And in your report you discuss the An Study which looked at 684
23 patients who received G2 Filters over a five-year span from
24 2005 to 2010. And you said the authors found filter fractures
25 in 13 of 684 patients, 1.9 percent. And again, I'm quoting

01:10PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Stein-Cross

1 your report, at five years fracture prevalence was estimated to
2 be 38 percent.

3 Have I correct correctly from your report?

4 A. Yes.

5 MR. COMBS: May I publish the ELMO again, Your Honor?

01:10PM

6 THE COURT: You may.

7 BY MR. COMBS:

8 Q. And I think your opinion in this case, as expressed in your
9 report is that these studies I have mentioned and other studies
10 you talked about in your report are unfairly biased against
11 Bard. Is that correct?

01:11PM

12 A. To a certain degree, yes.

13 Q. I'm sorry?

14 A. To a certain degree, yes.

15 Q. Certain degree.

01:11PM

16 MR. COMBS: Can you go to Page 15 of Dr. Stein's
17 report, Gay?

18 BY MR. COMBS:

19 Q. Specifically, you said on Page 15 of your report: Based on
20 my research there has been an unfair bias toward Bard filters
21 with overreaching and unjustified conclusions relying on low
22 quality research and sensationalized case studies.

01:11PM

23 That's what you said in your report, correct?

24 A. It's written there, yes.

25 Q. And did that comment include Bard's own study, the Binkert

01:11PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Stein-Cross

1 EVEREST Study?

2 A. No.

3 Q. Yes or no?

4 A. No.

5 MR. COMBS: You can take that down, Gay.

01:12PM

6 BY MR. COMBS:

7 Q. Want to talk about your case-specific opinions addressing
8 Mrs. Jones and what happened to her Eclipse Filter. Have you
9 ever seen -- well, you reviewed Mrs. Jones' medical records and
10 imaging in this case, correct?

01:12PM

11 A. Yes.

12 Q. And have you ever seen her -- any reports of her having
13 blood clots or problems with blood clots since the filter was
14 implanted in 2010?

15 A. No.

01:12PM

16 Q. And no problems with blood clots after the filter was
17 removed?

18 A. Not that I could see.

19 Q. You said in your report, and I can pull it up if you don't
20 recall, but that there is no force to push the strut through
21 the wall of the pulmonary artery. Do you recall seeing that?
22 I can pull up your report if you need.

01:12PM

23 A. Please.

24 MR. COMBS: If you could, Gay, go to Page 4.

25 BY MR. COMBS:

01:13PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Stein-Cross

1 Q. And if you see the last sentence of the paragraph there
2 that Gay is highlighting for you, you said: There is no force
3 to push the strut through the wall of the pulmonary artery.

4 A. Yes.

5 Q. Is that correct?

01:13PM

6 And you would agree, though, that the pulmonary artery
7 is the connection in the body between the heart and the lung?

8 A. Indirectly.

9 Q. I'm sorry?

10 A. To a certain degree, yes.

01:13PM

11 Q. To a certain degree?

12 A. Yeah.

13 Q. Is it yes or no? Is the pulmonary artery the connection
14 between the heart and the lung?

15 A. Well, there's the main pulmonary artery. Where the strut
16 is is a peripheral pulmonary artery. So it's not the same
17 thing. You are simplifying it.

01:13PM

18 Q. Well, you would agree that Mrs. Jones' fracture is located
19 in the space between her heart and her lung in her body?

20 A. The fracture, you mean the fragment or the filter?

01:14PM

21 Q. The fragment piece of the filter.

22 A. The fragment piece is in the pulmonary artery.

23 Q. That's between the heart and the lung? Yes or no.

24 A. What do you refer by lung? Lung contains a lot of
25 structures.

01:14PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Stein-Cross~~

1 Q. I think it's a pretty simple question, Doctor, and I have
2 asked you for a yes or no answer, please.

3 A. I can't answer yes or no.

4 Q. Thank you. But you would agree as a medical doctor that
5 you are aware that the heart beats and pushes blood through the
6 circulatory system around 80 times a minutes, which is about 42
7 million times per year?

01:14PM

8 A. Yes.

9 Q. And you would agree that the lungs breathe in and out
10 respirating about 16 times per minute, about eight million
11 times per year?

01:14PM

12 A. Yes.

13 Q. Let me ask you another simple yes or no question: Did Mrs.
14 Jones' Eclipse Filter fail? Yes or no.

15 A. It did not.

01:14PM

16 Q. And it is your expert opinion in this case at the time of
17 retrieval it was still functional?

18 A. Yes.

19 Q. And you would degree the filter tilted?

20 A. Slightly.

01:15PM

21 Q. Do you agree the filter caudally migrated?

22 A. No.

23 Q. So you would disagree if there's testimony in this case
24 from plaintiff's experts like Dr. Hurst, you would disagree
25 there was any caudal migration of her filter?

01:15PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Stein-Cross

1 A. I did not see his testimony, but if you are asking me if I
2 think that it migrated, I strongly disagree with that. I can
3 elaborate if you want me to.

4 Q. But you would agree with me that it did fracture?

5 A. Yes.

01:15PM

6 Q. And you haven't been shown or looked at any Bard internal
7 documents in your work for this case, have you?

8 A. No, I did not.

9 Q. And so are you aware that Bard describes tilt, migration,
10 and fracture as failure modes?

01:15PM

11 A. There's a structural failure or a clinical failure.
12 There's a difference.

13 Q. But it's your opinion, your opinion regardless of how Bard
14 defines failure, that Mrs. Jones' filter did not fail in this
15 case?

01:16PM

16 A. Clinically it did not fail. She did not have pulmonary
17 embolism.

18 Q. The fragment of Mrs. Jones' Eclipse Filter that broke off,
19 it had to travel through her heart in order to reach the
20 pulmonary vasculature, is that correct?

01:16PM

21 A. Correct.

22 Q. And you mentioned in your questioning with Mr. Rogers that
23 dizziness like she reported in April 2015 in the emergency room
24 could be caused by a cardiac event, correct?

25 A. Yes.

01:16PM

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Stein-Cross—

1 Q. And as the filter piece travelled up through her vena cava
2 into her heart through the chambers and valves of her heart
3 into her pulmonary artery it could have gotten stuck or lodged
4 there, is that correct?

5 A. No. It traveled through. It didn't get stuck.

01:16PM

6 Q. Could have, though, correct?

7 A. Unlikely.

8 Q. Not possible?

9 A. Very unlikely.

10 Q. But you would agree, of course, that if that had happened
11 that would be a bad thing, if it had got stuck in her heart?

01:16PM

12 A. That's a hypothetical question. It didn't happen. In
13 reality it didn't happen. I don't believe it happened.

14 Q. If it had happened, Doctor, would that have been a serious
15 event?

01:17PM

16 A. In the unlikely possibility, yes.

17 Q. That could cause lots of problems?

18 A. Again it's a very hypothetical if. It's very unlikely. So
19 I'm not sure -- you are asking me a lot of unlikely
20 hypothetical questions. How am I supposed to answer that?

01:17PM

21 Q. So even if the filter piece -- I'm sorry -- even if Mrs.
22 Jones' Eclipse Filter didn't fail under your standards, the
23 fragment embolizing up through her vena cava into and through
24 her heart could have killed her, couldn't it?

25 A. It did not.

01:17PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Stein-Cross

1 Q. Could have, couldn't it?

2 A. I don't think so. There's no report of fatalities out
3 there.

4 MR. COMBS: No further questions, Your Honor.

5 THE COURT: Redirect?

01:17PM

6 MR. ROGERS: Very briefly, Your Honor.

7 REDIRECT EXAMINATION

8 BY MR. ROGERS:

9 Q. Dr. Stein, you were asked some questions about the An
10 article. Do you recall that?

01:18PM

11 A. Yes.

12 Q. Is that a piece of medical literature that you are familiar
13 with?

14 A. Yes, I am.

15 Q. I'm going to put this back up on the ELMO.

01:18PM

16 MR. ROGERS: And, Your Honor, can we display that to
17 the jury, please?

18 THE COURT: Yes.

19 BY MR. ROGERS:

20 Q. Now, on this piece of paper, that has got an An, it says
21 five years fracture 38 percent. Do you see that, Doctor?

01:18PM

22 A. Yes, I do.

23 Q. And in the An Study, what was the reported fracture rate
24 that the authors reported in the medical literature based on
25 the current data that they had?

01:18PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Stein-Redirect

1 A. I think it was more like 1.2 percent.

2 Q. 1.2?

3 A. Yeah.

4 Q. Does 1.9 sound about right?

5 A. Yeah. Yeah. Sorry. 1.9.

01:18PM

6 Q. So I'm going to strike through this and put 1.9 percent.

7 Now, plaintiff's counsel put on the screen five year
8 fracture, 38 percent.

9 A. Yes.

10 Q. Can you explain that to the jury?

01:19PM

11 A. Sure. So they use something that is called a Kaplan-Meier
12 analysis. So with the way the Kaplan-Meier analysis works is
13 that you basically take the fractures and the sample size at
14 every interval. So the problem with this analysis is that it
15 tends to exaggerate the rate at the end because the sample size
16 is very small. So at five years you are not going to have a
17 lot of patients. So therefore, the percentage is going to be
18 artificially high. And I think it is misleading. It creates a
19 false impression. And I think it very unfortunate that a lot
20 of literature quotes that particular number which I question
21 greatly. I am more with the 1.9 percent.

01:19PM

01:19PM

22 Q. I understand. Let me ask you this: So this 38 percent as
23 reported, was that a prediction of what would happen in the
24 future or was it something that was based on current data that
25 was available at that time?

01:20PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Stein-Redirect~~

1 A. I think it's an extrapolation. I think it's kind of an
2 over-analysis or confusing statistics to manipulate and
3 sensationalize the data is the way I perceive it.

4 Q. Since this article was published, are you aware of any
5 study that has come along since then that would publish a rate
6 based on actual current data that would be anything close to 38
7 percent?

01:20PM

8 MR. COMBS: Objection, Your Honor. Nondisclosure.
9 He's got to specify the article he's talking about.

10 THE COURT: Overruled. Fair redirect.

01:20PM

11 THE WITNESS: No. I'm not aware of anything that
12 comes even close to that, nowhere close to that.

13 MR. ROGERS: Thank you. No further questions.

14 THE COURT: Thank you, Doctor. You can step down.

15 MR. NORTH: Your Honor, at this time we could call Dr.
16 Paul Briant to the stand.

01:20PM

17 THE COURT: Feel free to stand up, Ladies and
18 Gentlemen, if you want to.

19 MR. NORTH: May I approach?

20 THE COURT: Yes.

01:21PM

21 THE COURTROOM DEPUTY: Please stand right there.
22 Raise your right hand.

23 (The witness was sworn.)

24 THE COURTROOM DEPUTY: Could you please state your
25 name and spell it for the record?

01:21PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 THE WITNESS: Paul Briant. P-A-U-L, last name
2 B-R-I-A-N-T.

3 THE COURTROOM DEPUTY: Thank you. Please come have a
4 seat.

5 PAUL BRIANT,
6 called as a witness herein, having been duly sworn, was
7 examined and testified as follows:

8 DIRECT EXAMINATION

9 BY MR. NORTH:

10 Q. Good afternoon, Dr. Briant.

01:22PM

11 A. Good afternoon.

12 Q. Could you tell the members of the jury what your profession
13 is?

14 A. Sure. So I'm a mechanical engineer at Exponent Failure
15 Analysis Associates.

01:22PM

16 Q. Now, can you tell the jury about your educational
17 background which resulted in you becoming a mechanical
18 engineer?

19 A. Sure. So I got my Bachelor of Science degree in mechanical
20 engineering from Washington University in St. Louis where I
21 graduated summa cum laude. I then went on to Stanford
22 University where I got my Master's and my Ph.D., again, both in
23 mechanical engineering.

01:22PM

24 Q. What was the topic of your Ph.D. research?

25 A. So for my Ph.D., I looked at tissue mechanics so

01:22PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 understanding how tissues within the body will react to
2 mechanical loads and forces you put on them. The focus on that
3 was looking at cartilage and to understand the causes of
4 osteoarthritis.

5 Q. Are you a licensed engineer?

01:22PM

6 A. Yes. I'm a professional engineer.

7 Q. You said that you worked for Exponent Failure Analysis
8 Associates. Can you tell us what that company does?

9 A. Sure. So we're a technical consulting firm, and we focus
10 mostly on failure analysis.

01:23PM

11 Q. And where are your offices located?

12 A. So I'm in Menlo Park, California.

13 Q. How long have you been employed with Exponent?

14 A. I have been there for 10 years.

15 Q. Did you start there after you completed your doctorate?

01:23PM

16 A. Yes. I went there right out of school.

17 Q. What is your position with Exponent?

18 A. I'm a principal engineer.

19 Q. And what type of work do you do with the company?

20 A. So my work focuses on understanding the stresses and
21 strains inside of a structure. So I do strain analysis or
22 stress analysis. And this includes both calculations and
23 analytical finite element analysis and other testing as well as
24 custom laboratory bench testing.

01:23PM

25 Q. Do you work -- what sort of entities do you perform this

01:23PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 analysis for?

2 A. So we, and I, consult over a wide range of industries. My
3 work focuses largely on medical devices as well as electronic
4 devices.

5 Q. Are you familiar with a substance called Nitinol?

01:24PM

6 A. Yes.

7 Q. Have you had any involvement with Nitinol from a
8 professional standpoint?

9 A. Yes, I have, a lot.

10 Q. Have you ever had any experience with cardiovascular
11 Nitinol products?

01:24PM

12 A. Yes. So a large part of the medical device work that I do
13 is on implantable medical devices and understanding the
14 stresses and strains in those structures.

15 Q. Have you given presentations on Nitinol?

01:24PM

16 A. Yes.

17 Q. And have you written in any publications on Nitinol?

18 A. Yes. I have published papers on understanding, again, the
19 stresses and strains of Nitinol structures as well as analyzing
20 what we call the fatigue performance of Nitinol.

01:24PM

21 Q. Now, do you work with companies sometimes in the medical
22 device industry?

23 A. Yes. That's a big part of what I do.

24 Q. And what sort of projects do you do for companies in the
25 medical device industry?

01:25PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 A. Again, it varies, but a lot of the work that I do is on
2 implantable cardiac devices.

3 Q. And when you say "a lot of the work I do," is that testing
4 and analysis?

5 A. Yes. Both.

01:25PM

6 Q. Have you been retained by my law firm to assist in this
7 litigation?

8 A. I have.

9 Q. And have you been consulting with my firm for several
10 years?

01:25PM

11 A. I have.

12 Q. What were you specifically asked to do in this case?

13 A. So I was asked in this case to review the opinions and
14 claims put forth by Dr. McMeeking, who is the mechanical
15 engineering expert put forth by the plaintiffs and to review
16 the basis for those claims and the underlying calculations that
17 went into those bases.

01:25PM

18 Q. And who determined what your methodology would be in
19 undertaking this analysis?

20 A. I did.

01:26PM

21 Q. As a part of your work with Exponent do you also consult
22 with parties involved in litigation?

23 A. I do.

24 Q. Can you estimate for us what percentage of your
25 professional time is spent in litigation versus what percentage

01:26PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 is spent working directly with clients analyzing failure events
2 of their products?

3 A. Sure. So about 40 percent of my time is on litigation
4 related matters, and the remaining 60 percent of my time is on
5 working directly with corporations to understand their
6 products.

01:26PM

7 Q. Can you just give us a sampling of some of the medical
8 devices you have worked on in conducting failure analyses?

9 A. Sure. It ranges, but things like stents, heart valves,
10 catheter-based devices. So it covers a broad range.

01:26PM

11 Q. And I believe you mentioned that you have also done work
12 for the consumer electronics industry?

13 A. That's correct.

14 Q. And what sort of products have you worked on as far as
15 doing testing and analysis for that industry?

01:27PM

16 A. It, again, varies, but the core of it, the focus of it is
17 understanding how the products are going to perform when they
18 are in the field looking at things like broken solder joints,
19 things like that.

20 Q. Can you estimate how many medical devices you have
21 analyzed, tested, and reviewed as a part of your work at
22 Exponent over the last decade?

01:27PM

23 A. I don't have an exact number, but well over 100. Medical
24 device analysis, as I said, is a big part of what I do and
25 analyzing doing complicated analyses of medical devices under

01:27PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 real life scenarios is the --

2 Q. Have any of your analyses of various medical devices been
3 presented to the FDA as part of a device submission in the
4 past?

5 A. Yes. My work has been reviewed by the Food and Drug
6 Administration as part of submissions, and I have worked
7 directly with FDA reviewers during their -- if they have any
8 questions.

01:28PM

9 Q. What documents were you provided to review in this matter?

10 A. It was a range of materials. It included Bard files; it
11 included expert reports; it included depositions from other
12 experts, things like that.

01:28PM

13 Q. Were you provided materials regarding the development of
14 the Recovery, the G,2 the G2X, and Eclipse IVC filters?

15 A. Yes. Part of the materials was the 510(k) submissions, the
16 design history files, things like that.

01:28PM

17 Q. Were you provided testing materials?

18 A. Testing materials are part of those packages, yes.

19 Q. And how were the documents you received and reviewed
20 selected?

01:28PM

21 A. So I received an initial set of documents, and I received
22 documents throughout the course of this project. And if I
23 needed other documents I would just go ahead and request them.

24 Q. Did you review any expert reports or depositions in the
25 litigation?

01:29PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 A. Yes. I reviewed expert reports and depositions.

2 Q. Did you pay particular attention to the report and
3 depositions of Dr. McMeeking?

4 A. Yes. Those are certainly the focus of my role in this
5 case.

01:29PM

6 Q. And did you attempt to review most of the documents
7 referenced in Dr. McMeekings reports or depositions?

8 A. Yes. I don't know if I reviewed all of them, but I
9 certainly reviewed most of them.

10 Q. Now, Dr. Briant, as a part of your consulting work with me
11 and my firm in this case, have you actually performed testing
12 or analysis of Bard's IVC filters?

01:29PM

13 A. Yes. We have done both.

14 Q. Tell us what sort of testing and analysis you have done
15 over the years.

01:29PM

16 A. So the analyses have been finite element based strain
17 calculations which we'll be talking about. And the testing has
18 been experimental bench testing, so testing we do in the lab on
19 actual filters.

20 Q. Did that testing involve sophisticated equipment?

01:30PM

21 A. Yeah. As I said, the technique we use for our strain
22 calculations is called finite element analysis. And the test
23 equipment is also sophisticated.

24 Q. Doctor, you keep referencing "we." Did other professionals
25 at Exponent assist you with this testing and analysis?

01:30PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 A. Yes. I have a team that helped me with this.

2 Q. And what sort of professionals does that team consist of?

3 A. It consists of other engineers as well as technical staff.

4 Q. Now has your company charged for the testing and finite
5 element analysis and other calculations and work you have done
6 as a part of your work in this case?

01:30PM

7 A. Yes.

8 Q. Can you estimate how much Exponent has charged in total for
9 all of the analyses performed by this team of people over the
10 years?

01:31PM

11 A. Sure. So over the five years or so that we have been
12 involved in this project, it's totaled about \$650,000.

13 Q. Are you an employee or owner of Exponent?

14 A. I'm an employee.

15 Q. Do the billings that you have given to my law firm over
16 that five-year period reflect only your time?

01:31PM

17 A. No. It's myself and the team and also machine charges,
18 unit charges, things like that.

19 Q. Are you a salaried employee at Exponent?

20 A. Yes, I am.

01:31PM

21 Q. Is your compensation contingent in any way on the number of
22 hours you have worked on the filter analyses?

23 A. No, it's not. I get a salary whatever it is.

24 Q. Dr. Briant, as a result of the work and investigation that
25 you have done in this case, have you reached any opinions?

01:31PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 A. Yes, I have.

2 Q. And are those generally three major opinions?

3 A. Yes.

4 Q. Could you tell the members of the jury what your
5 principal -- three principal opinions are?

01:32PM

6 A. Sure. So as you heard from the plaintiff's expert, Dr.
7 McMeeking, he renders a series of criticism and claims about
8 the Bard filters, both in terms of the design of the filters as
9 well as the testing that Bard did during their design process.

10 And so my opinions boil down to three main things.

01:32PM

11 Number one is that the calculations that Dr. McMeeking
12 performed that underlie, or the foundation for his design
13 opinions, that those calculations are unreliable. And that's
14 due to the simplifications that Dr. McMeeking made when
15 performing those calculations as well as the assumptions that
16 were fed into that analysis which, as I will talk about, were
17 beyond physical limits of what the body can do. So that's
18 number one.

01:32PM

19 Number two is that Dr. McMeeking criticizes the
20 testing that Bard performed. However, the testing that Bard
21 did considered all the relevant complications that are known to
22 occur with IVC filters. And in addition, while Dr. McMeeking
23 criticized the testing, he didn't put forth any analysis or
24 engineering bases for alternative test methods that might be
25 used or any alternative designs, for that matter.

01:33PM

01:33PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 Q. And what was your third opinion, Dr. Briant?

2 A. Sure. So my third opinion was that the Simon Nitinol
3 Filter, the SNF that you have heard about, is not an
4 alternative design from an engineering perspective because it
5 lacks the retrievability of that functionality that Bard
6 filters have.

01:33PM

7 MR. NORTH: Could we display Exhibit 7944, please.

8 BY MR. NORTH:

9 Q. Can you identify for us what 7944 is?

10 A. Sure. This is a slide I put together that summarizes the
11 opinions that we just discussed.

01:33PM

12 MR. NORTH: Your Honor, at this time we would seek
13 permission to display 7944.

14 THE COURT: As a demonstrative exhibit?

15 MR. NORTH: As a demonstrative, yes.

01:34PM

16 THE COURT: Any objection?

17 MR. STOLLER: No objection.

18 THE COURT: You may.

19 BY MR. NORTH:

20 Q. Here, do you list the three opinions that you just
21 explained for us?

01:34PM

22 A. Yes. On the left-hand side is a summary of those opinions.

23 Q. And are those opinions taken from your report in this
24 litigation?

25 A. Yes, they are.

01:34PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 Q. And I think we'll talk about these in more detail in a
2 minute. But tell us briefly what you are trying to show with
3 these pictures or pictographs on the right.

4 A. Sure. So on the right-hand side, those images are related
5 largely to opinion number one. And they sort of highlight the
6 difference in the analyses that were performed. So Dr.
7 McMeeking, in his calculations, incorporated just a single
8 filter arm explicitly in his analysis, and actually just the
9 upper portion of the arm from the tip to the elbow.

10 And in the calculations that we did, we had the entire
11 filter, and more importantly, we also had the surrounding soft
12 tissues. So we had the IVC; we had the surrounding abdominal
13 tissues and the vertebrae. And that's depicted in the images
14 in the center column.

15 Q. Let me ask you this, Dr. Briant: As part of your work in
16 this case have you examined actual Bard filters?

17 A. Yes, I have.

18 Q. What kinds of Bard filters have you looked at?

19 A. So I have looked at Recovery, G2, and Eclipse Filters.

20 Q. And what did you do with the Bard filters that you were
21 provided?

22 A. We did the mechanical bench testing as I talked about to
23 validate our calculations.

24 Q. And what was the purpose of that mechanical bench testing?

25 A. It was to validate the analyses. So an important part when

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 you do calculations like this to try and understand the strains
2 and structures is to make sure that your calculations are
3 representative, are consistent with real world data. So that's
4 what that bench testing was for.

5 Q. Now, have you read any materials in this litigation
6 specific to Mrs. Jones, the plaintiff in the case?

01:36PM

7 A. I have read other expert reports specific to her.

8 Q. Do you know what type of filter Mrs. Jones had implanted?

9 A. It was an Eclipse Filter.

10 Q. And do you have an understanding of the type of events or
11 complications that Mrs. Jones has been reported as having with
12 her Eclipse Filter?

01:36PM

13 A. Yes. My understanding is she had a tilt of about four
14 degrees and she had a strut fracture. And the strut moved to
15 her right pulmonary artery.

01:36PM

16 Q. Dr. Briant, let's talk further about your first opinion
17 regarding the strain analysis performed by Dr. McMeeking.

18 I believe you told us that something about he analyzed
19 only part of an arm. Is that correct?

20 A. That's correct.

01:37PM

21 Q. What about that analysis and only looking at part of the
22 arm do you criticize?

23 A. So there's several things that I criticize, and we'll go
24 into more detail about them, I'm sure. But as I said, he only
25 looked at a portion of the arm. And the biggest thing here is

01:37PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 it didn't include the surrounding the issue, so the environment
2 that the arm was in. So he had to make assumptions on how that
3 arm was going to be loaded by the IVC as opposed to having a
4 more complete picture with the surrounding environment that the
5 filter lives in.

01:37PM

6 Q. Why did these incorrect assumptions that Dr. McMeeking made
7 in your view, why did those matters?

8 A. So as you will see, he -- the assumptions that he made were
9 beyond what the human body can do. So he assumed essentially
10 that the IVC was infinitely stiff; that it would move
11 regardless whether there's a filter there or not by the same
12 amount. And in addition, he assumed that wherever the filter
13 contacted the IVC, that that point was essentially constrained
14 from rotation so it was kind of locked and the filter just had
15 to go wherever the IVC went. So this resulted in an
16 overprediction of his strains, or higher strains than what you
17 would get with actually incorporating the environment.

01:38PM

01:38PM

18 Q. Now, you conducted filter arm strain and stress analysis,
19 correct?

20 A. That's correct.

01:38PM

21 Q. Can you tell us in general terms what that means or
22 consists of?

23 A. Sure. That involves solving fundamental equations to
24 calculate the stresses or the strains inside of a structure.

25 Q. Did Dr. McMeeking also analyze filter arm strain and

01:38PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct

1 stress?

2 A. Yes, he did.

3 Q. And how did he do his analysis?

4 A. So he did a series of analytical calculations. That was
5 the bulk of the work, and then he also did some finite element
6 analysis.

01:38PM

7 Q. Did you see any evidence that Dr. McMeeking conducted
8 mechanical bench testing to verify his initial calculations?

9 A. No, he did not.

10 Q. Did you do that?

01:39PM

11 A. Yes. We did the bench testing to validate the
12 calculations.

13 Q. What, in particular, was Dr. McMeeking evaluating about arm
14 strain?

15 A. He was calculating the strains in the filter arm with a
16 focus near the cap.

01:39PM

17 Q. Do you have any criticisms of his including only the upper
18 arm in doing those calculations?

19 A. Well, as I said he has just the upper arm and so therefore,
20 had to, in order to simplify it down to that, had to make a
21 series of assumptions, and the biggest one being that he didn't
22 incorporate the surrounding IVC and tissues and had to make
23 assumptions about how the filter would be loaded.

01:39PM

24 Q. When you did your computer modeling, did you utilize the
25 entire filter as opposed to just one arm?

01:40PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 A. Yes. We had the entire filter in there.

2 Q. Did you create a demonstrative exhibit taken from your
3 report to help you explain some of the assumptions?

4 A. Yes, I did.

5 MR. NORTH: Could we display 7812?

01:40PM

6 Your Honor, at this time we would seek leave to
7 display 7812 as a demonstrative.

8 MR. STOLLER: No objection.

9 THE COURT: You may.

10 BY MR. NORTH:

01:40PM

11 Q. And this is essentially the pictures we saw on the summary
12 of your opinions, aren't they?

13 A. That's correct.

14 Q. And did you utilize these to show a difference between how
15 you -- the assumptions you made versus the assumptions Dr.
16 McMeeking made?

01:40PM

17 A. Correct.

18 Q. And explain that for us, what that difference is.

19 A. Sure. Again, as we talked about, so the calculations by
20 Dr. McMeeking had just the single filter arm and, most
21 importantly, did not have the surrounding soft tissues. He
22 didn't model those as deformable. He assumed they were
23 essentially infinitely stiff, so they would move regardless of
24 whether the filter was present and didn't allow the filter to
25 really interact with the IVC the way it would naturally.

01:41PM

01:41PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 In the calculations that we did, we had the whole
2 filter and then we had the surrounding soft tissues. The IVC
3 is shown in blue, it's is that blue ring. So the image in the
4 center there, we're looking down on our analysis. The filter
5 is in the center. You can see the struts emanating out. The
6 IVC is shown in blue and then we have the surrounding soft
7 tissues that are shown in green. And we also included a
8 vertebrae, because it's nearby.

01:41PM

9 And then we loaded this in different ways in order to
10 try to bound the problem. So we looked at it from not just a
11 single loading scenario but several loading scenarios to try
12 and understand and capture the entire range of strains that
13 might be present on the filter.

01:42PM

14 Q. Dr. Briant, what impact on the analysis do you believe that
15 your use of the complete filter as opposed to just a single
16 upper arm like Dr. McMeeking did had on the calculations and
17 analysis?

01:42PM

18 A. Sure. So certainly including the environment that the
19 filter lives in allows for both a more accurate set of
20 calculations and strains. In addition, the assumptions that
21 Dr. McMeeking used in his calculations, as I said, were beyond
22 what the human body can do. So this would lead to an
23 overprediction or higher strain than you would actually expect
24 to happen.

01:42PM

25 MR. NORTH: If we could pull up 7183, please.

01:42PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct

1 BY MR. NORTH:

2 Q. You have mentioned the importance of the surrounding
3 tissues which you considered in your analysis. Is 7813 a
4 demonstrative you prepared to explain the importance of the
5 surrounding tissue aspect of the analysis?

01:43PM

6 A. Yes.

7 MR. NORTH: Your Honor, at this time we would seek to
8 display 7813 as a demonstrative exhibit.

9 MR. STOLLER: No objection.

10 THE COURT: You may.

01:43PM

11 MR. NORTH: Thank you.

12 BY MR. NORTH:

13 Q. Now, on the right side, that's the sort of diagram of the
14 entire filter in the IVC that you showed us earlier, correct?

15 A. That's correct.

01:43PM

16 Q. Tell us what we're looking at on the left side and what the
17 importance of that is.

18 A. Sure. So what we're looking at on the left side is a CT
19 scan. This was taken from medical literature. But this is put
20 together to explain the motivation and to explain the geometry
21 and why we set up the model the way we did.

01:43PM

22 So what you can see in the center, kind of near the
23 bottom, is a bright region and that's a part of the spine.

24 That's a vertebrae. A little above and to the left of that

25 where you can see two yellow arrows pointing down is an

01:44PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 ellipse, and that's the IVC. So you can see where the IVC
2 lives in the abdomen surrounded by soft tissues in that region.
3 You have abdominal tissues. You have the kidneys, things like
4 that.

5 So you can imagine translating this over, and this was 01:44PM
6 the motivation behind the model setup that we did where we have
7 the filter, we have the IVC, and then we have the surrounding
8 soft tissues with the vertebrae.

9 Q. Did you make a different assumption than Dr. McMeeking did
10 on how the tissue and filter would interact in the human body? 01:44PM

11 A. Yes, as we talked about. So we allowed the filter to
12 interact with it, and because we have deformable soft tissue so
13 the filter will push against the IVC and deform it as opposed
14 to assuming the IVC is infinitely stiff and that the IVC will
15 just control wherever the filter goes. 01:45PM

16 Q. As a part of your work in studying mechanical engineering
17 issues, are you familiar with medical literature that
18 substantiates or supports your assumptions about the impact of
19 the surrounding tissues?

20 A. Yes. And this is in two ways. On the front end there's 01:45PM
21 medical literature where they have gone in and tested the
22 properties of these tissues to understand how stiff they are,
23 and that's what we use as input into our analysis. And then on
24 the back end there's been studies where they have looked at the
25 motion of the IVC and the people that have filters in them, and 01:45PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 they have shown that at the location of filter the IVC moves
2 less than away from the filter.

3 Q. What is hyperelastic response? What does that mean?

4 A. So that's a type of a stress-strain constitutive response
5 that tissues often show.

01:45PM

6 Q. If we could pull up 7945.

7 Is this a demonstrative you prepared in your report to
8 illustrate the hyperelastic response for the IVC?

9 A. Yes, it is.

10 MR. NORTH: Your Honor, at this time we would seek
11 permission to display 7945 as a demonstrative exhibit.

01:46PM

12 MR. STOLLER: No objection.

13 THE COURT: You may.

14 MR. NORTH: Thank you.

15 BY MR. NORTH:

01:46PM

16 Q. Tell us what this graph depicts, if you would, please.

17 A. Yes. So we're getting very mathy here. So what we have is
18 this plot here where on the X axis we have strain. And I don't
19 know that we have gone through defined stress and strain yet.

20 So strain is a measure of how much an object deforms when you
21 load it. So you imagine you have an object and you apply
22 weight to it. The weight is the force and stress is the
23 measure of the force that is applied. Strain is a measure of
24 how much the object will stretch, so it's a measure of
25 deformation. Stiffness is the ratio of those two things. So

01:46PM

01:47PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct

1 an object that is very stiff deforms very little under the same
2 force. Steel is very stiff and has a high stiffness. Rubber,
3 on the other hand, is very soft and has a low stiffness.

4 So going back here to the plot, what we're looking at
5 is what we call a stress-strain response of the tissue. So on
6 the X axis we have the strain, and on the Y axis we have the
7 stress, which is the vertical axis. So what you can see is
8 initially the tissue is very soft. It's that low region and
9 then eventually it stiffens up. And this is due to initially
10 the collagen fibers within the tissue are not particularly
11 organized. And then you pull on it and the fibers become
12 aligned, and so that's why you can get this change and this
13 increase in the stiffness once you are actually pulling on the
14 fibers themselves.

15 Q. What is this reference to modified data from Fung?

16 A. Fung is a textbook that we pull the data from.

17 Q. And what is this reference to Marlow fit for analysis?

18 A. So Marlow is a particular type of equation you can use to
19 fit these types of curves. So that was what was input into the
20 FEA.

21 Q. Now, did you take, in doing your stress-strain analysis on
22 the Bard filters, did you take into account the hyperelastic
23 response for the IVC?

24 A. Correct. So this is one of the material properties or
25 direct inputs into the analysis. So again, rather than

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct

1 assuming the IVC was infinitely stiff or rigid, we incorporated
2 this data which is from the literature about how the tissue
3 responds to load.

4 Q. Did that make your particular analysis different from the
5 one conducted by Dr. McMeeking?

01:48PM

6 A. Yes. For what I was just talking about in having a
7 deformable tissue that surrounds it based on this data from the
8 literature as opposed to making an assumption about how the IVC
9 would respond. And this allows us to, again, calculate the
10 response of the filter and the IVC together and not just have
11 to assume a certain value.

01:49PM

12 Q. Now, are there certain attributes unique to Nitinol as a
13 substance that you considered in your assumptions that differed
14 from those made by Dr. McMeeking as well?

15 A. Yes. So Nitinol is a special material. It's what we call
16 superelastic so it's kind of very stretchy compared to most
17 other metals. So in the calculations that we did, we took that
18 into account whereas Dr. McMeeking assumed that the material
19 was linear elastic.

01:49PM

20 Q. If we could bring up 7677, please.

01:49PM

21 Is this a demonstrative slide of graphs taken from
22 your report that illustrate the special properties of Nitinol?

23 A. Yes, it is.

24 MR. NORTH: Your Honor, at this time, we would seek
25 permission to display Exhibit 7677 as a demonstrative.

01:49PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct

1 MR. STOLLER: No objection, Your Honor.

2 THE COURT: You may.

3 BY MR. NORTH:

4 Q. What is a Nitinol constitutive relationship?

5 A. Yes. So the Nitinol constitutive relationship is, again,
6 the stress-strain response of the material. So what we're
7 looking at here, its curves are very similar to what we're
8 looking at. We have strain on the horizontal axis for both of
9 them and we have stress, which is the force, again, on the Y
10 axis.

01:50PM

01:50PM

11 And so what happens with Nitinol is you start in the
12 bottom left corner at 00 and you load it up. And it's
13 initially got a stiffness that's rather stiff, and then it goes
14 through this phase transition. And that's where you get that
15 horizontal portion of the curve where it becomes very soft.
16 And this is a very useful property for cardiovascular medical
17 devices. The reason these are often used for these devices is
18 because you can crimp it down to something very small and they
19 feed it into the body, and then it will spring back to its
20 original shape as opposed to other metals which won't do that.

01:50PM

01:51PM

21 Q. In making his calculations, did Dr. McMeeking take into
22 account the unique properties of Nitinol that you have just
23 discussed?

24 A. In his strain calculations, no, he did not.

25 Q. Did you consider it important to try to -- when trying to

01:51PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 make an accurate calculation of stress and strain to take into
2 account the unique qualities Nitinol?

3 A. Yes. So for IVC filters, the loads that they go under both
4 during crimp when they are loaded onto the catheter as well as
5 during cyclic loading at the extreme levels I calculated and 01:51PM
6 that he calculated, in both of those cases superelasticity
7 would be needed to get an accurate result.

8 Q. Dr. Briant, is it well known in the mechanical engineering
9 and material sciences communities that Nitinol has these unique
10 superelastic properties? 01:52PM

11 A. Yes, it is.

12 Q. Do you have any understanding from what you have reviewed
13 as to why if that is well known Dr. McMeeking did not take that
14 into account in his analysis?

15 A. No, I don't. 01:52PM

16 Q. How did your analysis differ from Dr. McMeeking's with
17 regard to filter geometry?

18 A. Sure. So as we talked about, in terms of the filter
19 geometry, Dr. McMeeking just had the single arm exclusively
20 incorporated into his analysis up to the elbow whereas we had 01:52PM
21 the entire filter.

22 Q. Were there any different assumptions that you and Dr.
23 McMeeking made with regard to motion of the filter?

24 A. Sure. So this is what I was talking about before where Dr.
25 McMeeking, in order to simplify things down and just have the 01:53PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 single arm and do things analytically rather than using the
2 finite elements, he had to make these assumptions in order to
3 make these simplifications and assume that the filter would
4 move a certain amount exactly as the IVC was moving beforehand
5 rather than allowing to deploy the filter into the environment
6 and allow the forces to balance out and actually calculate what
7 that motion would be.

01:53PM

8 Q. Does the filter actually impact the movement or pulsation
9 of the IVC?

10 A. It depends on the diameter of the IVC that you are looking
11 at, but it certainly can.

01:53PM

12 Q. And how can it impact it?

13 A. So when you squeeze the filter down, you really have to
14 squeeze it down in order to get it into the IVC. The filter
15 naturally wants to be bigger than the IVC. So you squeeze it
16 down, and that creates a force to do that. So the filter is
17 then pushing back against the IVC, so when loads come on to the
18 IVC to try and compress it, the filter is creating an external
19 load outwards. So that resists the motion so it reduces the
20 amount of pulsation you would get than if the filter wasn't
21 there.

01:53PM

01:54PM

22 Q. Why are these assumptions important in your view to the
23 analysis of strains with regard to these filters?

24 A. Sure. In order to be able to accurately calculate the
25 strains we would want to take this into account because it is

01:54PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 very important. And the assumptions that Dr. McMeeking made
2 are overly conservative and resulted in overprediction of the
3 strains.

4 Q. Did the different assumptions that you have outlined for us
5 regarding the geometry, regarding the tissues, regarding the
6 superelastic property of the Nitinol and these other
7 assumptions, did those produce different results in your
8 calculations than those obtained by Dr. McMeeking?

01:54PM

9 A. Yes, they did.

10 Q. If we could bring up 7816, please.

01:54PM

11 Is this a demonstrative exhibit you prepared taken
12 from your report that illustrates the differences in your
13 calculations with those of Dr. McMeeking?

14 A. Yes, it is.

15 MR. NORTH: Your Honor, at this time we would seek
16 permission to display 7816 as a demonstrative exhibit.

01:55PM

17 MR. STOLLER: No objection, Your Honor.

18 THE COURT: You may.

19 MR. NORTH: Thank you.

20 BY MR. NORTH:

01:55PM

21 Q. Explain to us what you are depicting on the left, first of
22 all.

23 A. Sure. So on the left is two images from different analyses
24 that we did. So these are direct outputs from the finite
25 element analysis software. Again, you put in the geometry, you

01:55PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 put in your properties for the tissues, and it calculates out
2 what the response would be.

3 And so what you can see on the left is two cases. We
4 looked at both a not perforated filter and a perforated filter.
5 And what I will draw your attention to is you can see that 01:55PM
6 where the arms contact the IVC, where the elbows of the arms
7 contact the IVC, you can see that the IVC has bulged there
8 because the filter arms are pushing outwards. And this is the
9 response that I was talking about where the filter will push
10 out against the IVC and change the motions when you apply an 01:56PM
11 external load.

12 Q. So did you perform your calculations in two different ways
13 once assuming, in the first instance, assuming that the filter
14 was not perforating the IVC and second assuming that it was?

15 A. Yes. That is correct. 01:56PM

16 Q. And does the second picture, B, depict the test that would
17 have been analyzed with perforation occurring?

18 A. Correct. That's the analysis with perforation.

19 Q. And how much perforation did you assume in your
20 calculations in that scenario? 01:56PM

21 A. So you can see here we have basically perforated up until
22 about halfway up the upper arm. We looked at perforation
23 levels from the elbow and upward. So we look looked at several
24 different scenarios.

25 Q. Now, tell us what the chart on the right shows. 01:57PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 A. Sure. So this is a bar graph. And the primary thing we're
2 looking at is comparing the calculations using Dr. McMeeking's
3 assumptions versus there was also the calculations under the
4 same conditions when you incorporate the deformable nature of
5 the IVC and the environment that the filter lives in.

01:57PM

6 So what we have are the three different pairs of bars,
7 and those are for three different amounts of pulsation of the
8 IVC. So you can imagine the IVC pulses every time you breathe.
9 And so we looked at various levels of that. We looked at one
10 millimeters pulsation and then we looked at 18 and 50 percent.
11 And that refers to -- the percent there is how much it pulses
12 relative to its initial diameter.

01:57PM

13 On the vertical column, on the Y axis, we have the
14 strain amplitude, which is how much strain you are getting
15 every time the IVC pulses. So the red bars are the results
16 from Dr. McMeeking's evaluations, and blue bars are the results
17 from our calculations when you have the whole filter and
18 surrounding tissue and things like that.

01:57PM

19 Q. Am I correct that at 50 percent Dr. McMeeking's
20 calculations are almost eight times -- having the stress or
21 strain at eight times greater than Exponent's calculations?

01:58PM

22 A. It appears to be about that.

23 Q. Can you estimate approximately how much greater at 18
24 percent Dr. McMeeking's strain calculations were than what
25 Exponent conducted?

01:58PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct

1 A. I don't know the numbers off the top of my head, but it
2 looks like it's about the same ratio.

3 Q. Was it also significant at one millimeter?

4 A. Yes. In all cases you can see that when you assume both
5 that the IVC motion doesn't change and that the IVC is so stiff
6 that it locks the rotation of that filter so it has to -- the
7 filter just has to move where the IVC goes, then you get a big
8 overprediction in the strains.

01:58PM

9 Q. And what is your opinion as to why Dr. McMeeking's
10 calculations are so much greater than what Exponent determined?

01:59PM

11 A. Well, again, it's because of the assumptions that were used
12 in order to be able to simplify and do the calculations by hand
13 rather than doing the finite element analysis.

14 Q. We talked earlier about the fact that Dr. McMeeking in his
15 analysis did not consider the superelastic nature of Nitinol.
16 Did he make any other assumptions about the Nitinol wire that
17 Bard used in its filters?

01:59PM

18 A. Yes. So once you do these calculations, you can compare
19 them to what's called the fatigue strength of the material
20 which is how strong the wire is in a fatigue scenario where you
21 are getting lots of cycles. And he assumed a value for this,
22 for this fatigue strength that was based on literature rather
23 than using fatigue strength data that came from testing that
24 Bard actually performs.

01:59PM

25 Q. Were Bard's actual test values for the fatigue strength of

02:00PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct

1 the Nitinol wire actually used in Bard filters, was that
2 available to Dr. McMeeking?

3 A. Yes, it was.

4 Q. Are you aware that Dr. McMeeking has testified in this case
5 that he instead consulted a literature review to determine
6 values?

02:00PM

7 A. Yes, I am.

8 Q. By using what he found in the literature to determine those
9 strain values rather than the actual data available to him for
10 wires used in Bard filters, did that affect the outcome of Dr.
11 McMeeking's calculations?

02:01PM

12 A. So what it affects is the implications of his calculations.
13 So as we have been talking about this whole time, he used
14 highly conservative values that are beyond physical limits and
15 got an overprediction of his strains. He then took a book
16 value for the fatigue strength that was way low. And rather
17 than using actual, you know, the actual environment of the IVC
18 and not overpredicting the strains and using the testing that
19 Bard did, taking both the overprediction of the strains and the
20 very low book value overstates the implications of his
21 calculations.

02:01PM

02:01PM

22 Q. I believe you have told us that you then did bench testing
23 on actual Bard filters following your stress and strain
24 calculations?

25 A. That's correct.

02:01PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 Q. And that Dr. McMeeking did not go that extra step?

2 A. No, he did not do any bench testing.

3 Q. Why did you decide to go, even after you had done this very
4 complicated analysis of stress and strain, why did you decide
5 to go further and do actual bench testing?

02:02PM

6 A. We did it because we wanted to verify our analyses and make
7 sure that our calculations lined up with actual results from
8 filters.

9 Q. And did the bench testing you performed actually validate
10 your calculations?

02:02PM

11 A. Yes. We got very good agreement.

12 Q. If we could bring up Exhibit 7815, please.

13 Dr. Briant, is 7815, does this contain pictures and
14 graphs from your report that demonstrate the bench testing that
15 you did?

02:02PM

16 A. Yes, it does.

17 MR. NORTH: Your Honor, at this time we would seek
18 permission to display Exhibit 7815 as a demonstrative exhibit
19 for the jury.

20 MR. STOLLER: No objection, Your Honor.

02:02PM

21 THE COURT: You may.

22 BY MR. NORTH:

23 Q. Explain to the members of the jury what this is showing us.

24 A. Sure. So this is showing the bench testing that we did,
25 the test setup. And so what we have on the left is a picture

02:03PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 of the setup. So you can see the actual filter that we have
2 there. This is a G2. You can see we're holding it by the cap.
3 And then what we have is a rod that's coming down from the top,
4 and this is attached to what's called an Instron machine, which
5 is a testing machine. And so that machine brings the rod down 02:03PM
6 into contact with the filter and then pushes on the arm, and we
7 also did legs, and then measures what's called the force
8 displacement response. So it measured the amount of force it
9 takes to compress the arm a certain amount.

10 Q. Now, what does this graph on the right side show us? 02:03PM

11 A. That's a result from one of the tests. So similar to what
12 we looked at before, this is showing displacement on the
13 horizontal axis. So that's how much the rod has moved down as
14 it comes down. And the vertical axis we have the force, how
15 much force it took to do that. And the experimental results 02:04PM
16 are shown by the solid lines there and you can see compared to
17 the FEA result, which is the black dash line. And you can see
18 we got very good agreement.

19 Q. I want to be sure I understand this. The FEA line, does
20 that represent the actual finite element analysis strain 02:04PM
21 calculations you made?

22 A. Correct. So what we do is we simulate this test on the
23 bench, that we did on the bench, we simulate that with our FEA
24 model. And then we pull out the same corresponding parameter
25 and do this comparison. 02:04PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct

1 Q. When it says "experiment," is that the actual bench
2 testing?

3 A. Correct. That's directly from the machine.

4 Q. Does that demonstrate the results from the two types of
5 tests are virtually identical?

02:04PM

6 A. It demonstrates that the calculations and the way we set up
7 the model is valid and representative of reality.

8 Q. Did you do anything else to verify the accuracy of your
9 calculations?

10 A. So again, we compared our results to literature. And this
11 is what I was talking about before where clinical studies have
12 been done with people that actually have filters in them. And
13 they have gone in and measured how much motion you get of the
14 IVC during various maneuvers. And so what they found was that
15 when they measured the pulsation of the IVC both above and
16 below the filter, they got more than when they measured the
17 pulsation right where the filter is.

02:05PM

02:05PM

18 So this demonstrates that the filter is reacting to
19 the tissues in keeping the IVC open compared to above and below
20 where the filter is not.

02:05PM

21 Q. Dr. Briant, did you also review some analysis that Dr.
22 McMeeking did relative to tilt?

23 A. Yes, I did.

24 Q. What was it that Dr. McMeeking did?

25 A. So for tilt, Dr. McMeeking, again, did some analytical

02:05PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 calculations as well as some finite element analysis work.

2 Q. Are those basically just by hand?

3 A. Yes. So those are hand calculations.

4 Q. And did -- what sort of assumptions did he make in making
5 those calculations regarding tilt?

02:06PM

6 A. Sure. So when performing those tilt analyses, again, he
7 was looking at how much the filter, how easily it is to tilt
8 the filter. When performing those calculations, he didn't
9 include several things that would resist the tilting motion.

10 Number one, he assumed that the interaction between the IVC and
11 the filter was frictionless so there was no friction at that
12 interaction. He, again, assumed that the IVC was rigid, so it
13 was perfectly smooth, as opposed to this tenting where you saw
14 where you get bulging where the filter makes contact, and that
15 would resist tilting.

02:06PM

02:06PM

16 And the last one is he didn't look at the effect of
17 how the foot would have to be disengaged from the wall. So as
18 you may have seen, the filters have little feet on the bottom
19 that engage with the filter wall, and the foot would have to
20 become disengaged in order for it to tilt.

02:07PM

21 Q. Are you critical of any of those assumptions made by Dr.
22 McMeeking?

23 A. Oh, yes. They would all resist tilting. And in order to
24 make the claim that the filter would easily tilt, one would
25 want to look at these effects rather than just ignoring them.

02:07PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 Q. Did Dr. McMeeking perform any bench testing to try to
2 confirm his hand calculations regarding tilt?

3 A. No, he did not.

4 Q. Does his analysis provide any information or data to assist
5 in determining how frequently Bard filters may tilt?

02:07PM

6 A. No, it wouldn't.

7 Q. Did you conduct your own analysis of tilt?

8 A. Yes. We did tilting analyses also.

9 Q. Can you explain to us what you did to try to analyze tilt?

10 A. Sure. So again, we looked at the -- how much force it took

02:08PM

11 to tilt the filter. We, again, used the same model setup that

12 we had in the previous calculations, so we had the entire

13 filter in an IVC in surrounding tissues. We looked at both

14 deformable IVC and surrounding tissues as well as a rigid one.

15 Q. Did you also do bench testing of a Bard filter to verify

02:08PM

16 your calculations regarding tilt?

17 A. Yes. We did bench testing as well, which is why we

18 simulated the rigid IVC in our calculations in order to be able

19 to compare that with the bench testing.

20 Q. Could we please bring up 7702.

02:08PM

21 Dr. Briant, does Exhibit 7702 reflect drawings taken
22 from your report to demonstrate the tilt analysis you
23 performed?

24 A. Yes, it does.

25 MR. NORTH: Your Honor, at this time we would seek

02:08PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 permission to display Exhibit 7702 as a demonstrative exhibit.

2 MR. STOLLER: No objection, Your Honor.

3 THE COURT: You may.

4 BY MR. NORTH:

5 Q. Explain to the members of the jury, Dr. Briant, what this
6 is showing us here.

02:09PM

7 A. Sure. So this is, again, looking at a direct output from
8 the finite element software. What we're looking at is a
9 cross-section of the model where we have -- we have run the
10 whole model then taken for the viewing purposes and cut it in
11 half. And what we're looking at on the left is the process
12 that we used for doing these tilt calculations.

02:09PM

13 So we deploy the filter in, and you can see on the
14 left side how it's vertical straight up and down. And we push
15 on the cap of the filter and look at how much force it takes to
16 do that.

02:09PM

17 Q. What do you mean with your reference to both rigid and
18 deformable IVCs?

19 A. Sure. So the deformable one would be using the
20 hyperelastic stress-strain response we saw before and using the
21 model setup we did during our strain calculations. We also
22 looked at a rigid IVC, and that was in order to be able to
23 compare for our bench testing. For our bench testing we used a
24 PVC tube for the IVC.

02:09PM

25 Q. And then you told us you did some bench testing regarding

02:10PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 or confirming your tilt calculations?

2 A. That's correct.

3 Q. Could we bring up Exhibit 7935, please.

4 Does 7935 reflect some drawings and photographs taken
5 from your report that help to explain the bench testing you did
6 with regard to tilt?

02:10PM

7 A. Yes, it does.

8 MR. NORTH: Your Honor, at this time we would seek
9 permission to display Exhibit 7935 as a demonstrative exhibit.

10 MR. STOLLER: No objection.

02:10PM

11 THE COURT: You may.

12 BY MR. NORTH:

13 Q. Dr. Briant, tell us what this photograph on the left is
14 showing.

15 A. So this is showing that the test setup that we did for our
16 tilt testing. So what you can see is we're looking down a tube
17 where the filter has been deployed, so you can see we're
18 looking at the cap of the filter and you can see the arms and
19 the legs coming off of that. This is inside a PVC pipe, as I
20 said.

02:10PM

02:11PM

21 And then what we did is we have a push rod very
22 similar to what we did in the force displacement testing where
23 we come in and push on the cap of the filter and measure the
24 amount of force that it takes to do that.

25 Q. Did it take more force or less force to tilt the Recovery

02:11PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct

1 Filter versus the G2 in the test you performed?

2 A. As you can see on the right-hand side, it took slightly
3 more force. What we're looking there at each of those plots
4 is, again, a force displacement response. So you can see on
5 the X axis for each one we have displacement of the cap, and on 02:11PM
6 the Y axis we have the force. And then the blue lines are the
7 experimental data from the testing while the black dash lines
8 are the FEA. As you can see, we got good agreement.

9 The two bottom plots are for G2 at two different tube
10 diameters and the two top plots are for Recovery Filters that 02:12PM
11 we tested, again, at different tube diameters.

12 Q. Again, did Dr. McMeeking do any bench testing such as this
13 regarding tilt?

14 A. No, he did not.

15 Q. What's your understanding of what Dr. McMeeking 02:12PM
16 testified -- or concluded with regard to tilt?

17 A. So he concluded that the filter could tilt easily.

18 Q. And are you critical of those opinions?

19 A. Yes, for the -- because of the basis for those opinions and
20 the analysis he did did not include all the things we talked 02:12PM
21 about in terms of the friction and the disengaging the foot.
22 In addition, Dr. McMeeking made other conclusions with regard
23 to tilt in terms of its role with perforation and the strains
24 on the filters.

25 Q. Did you reach any conclusion yourself as to how tilt might 02:12PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct

1 increase or decrease the strain on the filter and whether that
2 could lead to fracture?

3 A. Yes. So we did additional calculations beyond what we have
4 already talked about where we went in on our model and actually
5 tilted the filter and then repulsed the IVC and looked at the
6 change in the strains. 02:13PM

7 Q. Did you see any evidence in his work that was presented by
8 Dr. McMeeking to support his opinion that tilt somehow leads to
9 fracture?

10 A. So Dr. McMeeking's report made a claim that the strains
11 would increase when the filter gets tilted but he didn't
12 provide any calculations to support that claim. 02:13PM

13 Q. If we could bring up 7936, please.

14 Dr. McMeeking -- I mean Dr. Briant, can you identify
15 what Exhibit 7936 is showing? 02:13PM

16 A. That's showing a depiction of our tilted filter strain
17 calculations.

18 Q. Is that taken from your report?

19 A. It is.

20 MR. NORTH: Your Honor, at this time we would seek
21 permission to display Exhibit 7936 as a demonstrative exhibit. 02:14PM

22 MR. STOLLER: No objection, Your Honor.

23 THE COURT: You may.

24 MR. NORTH: Thank you.

25 BY MR. NORTH: 02:14PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 Q. Tell us what we're looking at here starting first from the
2 left -- first of all, is this depicting a G2 Filter?

3 A. Yes. This is a G2 Filter.

4 Q. And what are we showing on the left versus the right as to
5 not perforated versus perforated?

02:14PM

6 A. So again, we looked at both cases and we looked at both
7 perforated tilted filters as well as not perforated tilted
8 filters.

9 Q. And tell us what this overall shows as far as your analysis
10 goes.

02:14PM

11 A. Sure. So on the left you can see the not perforated case.
12 The filter barely tilts in that condition because the elbow
13 from the arms contact the wall almost right away. So you get
14 very little tilt.

15 In the perforated case we have a much larger tilt that
16 you can see there, and again, you can see when we -- in the
17 contracted state how the IVC is being resisted by the presence
18 of the filter. Now, down at the table on the bottom are the
19 results from the calculations, and so again, what we're looking
20 at is the strain amplitude, which is how much strain you get in
21 the filter as it pulses. And so on the next to last column we
22 have the results from before where it's straight up and down,
23 and you can see the strain amplitudes there. And in the right
24 most column we have the results from the tilted case, and you
25 can see the strain amplitudes are similar but actually slightly

02:15PM

02:15PM

02:15PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 lower in the tilted analysis.

2 Q. So does this show as according to your calculations and
3 testing the strain on a tilted filter is actually less than on
4 a not tilted filter?

5 A. It was similar but slightly lower, yes.

02:15PM

6 Q. Did you come to a conclusion about why that would occur?

7 A. So I expect it's due to the orientation of the strut arms.

8 So you can see in particular on the tilted case how the struts
9 are more horizontal, especially the one on the top. That would
10 reduce the actual stiffing effect and reduce the amount of
11 pulsation you would get for the filter itself.

02:16PM

12 Q. Did Dr. McMeeking's tilt analysis even look at the issue of
13 strain generated on the filter in tilt?

14 A. No. He didn't do any -- well, he mentioned in his report
15 that the strains would increase but didn't provide any
16 calculations. In addition, as we talked about, he had just a
17 single arm in his calculations. And in a situation like this,
18 doing -- using a single arm, one would not be able to calculate
19 the results in a tilted filter because you are no longer
20 symmetric, you are tilted. So a single arm doesn't work
21 anymore. It's no longer a valid assumption.

02:16PM

02:16PM

22 Q. Did your tilt analysis include a range that would include a
23 four-degree tilt?

24 A. Yes. So we looked at straight up and down, as you can see.

25 The non-perforated case is slightly tilted. I don't know

02:17PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct

1 exactly what the number is. But you can see in the perforated
2 case we looked at larger than four degrees.

3 Q. According to your calculations, would the strains at a
4 four-degree tilt be significant?

5 A. I think they would be very similar to a vertical filter. 02:17PM

6 Q. You have talked about your analysis of stress and strain
7 perforation and tilt in Recovery and G2 Filters. Does that
8 analysis have application to the Eclipse Filter?

9 A. Yes, it would, because the geometry of the struts in the
10 Eclipse Filter are the same as the geometry in the G2. The 02:18PM
11 only difference is the electropolishing that is performed for
12 the Eclipse Filter.

13 Q. How would you describe the stress and strains you
14 calculated that the G2 family of filters will experience?

15 A. As we talked about, using the -- incorporating the entire 02:18PM
16 environment that the filter lives in would give you much lower
17 strains than what Dr. McMeeking calculated.

18 Q. Let's move to your second opinion, if we could. And your
19 criticism, or your discussion of Dr. McMeeking's criticism of
20 Bard's testing and development process, have you developed over 02:18PM
21 the course of your career testing protocols in your work with
22 Exponent?

23 A. Yes. Experimental testing is a big part of what I do.

24 Q. What is your understanding of Dr. McMeeking's criticisms of
25 Bard testing? 02:19PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 A. He was critical of it.

2 Q. And do you agree with that criticism?

3 A. No, I don't.

4 Q. Did you have any comment about Bard's use or consideration
5 of the unique superelastic nature of Nitinol in its testing?

02:19PM

6 A. Well, I think that since Nitinol is superelastic you should
7 take it into account.

8 Q. Do you have responses to Dr. McMeeking's criticism
9 regarding the pulsation rates used by Bard in its testing?

10 A. No. Bard looked at a range of pulsation amounts in their
11 testing from one millimeter pulsation to much larger as well.

02:19PM

12 Q. Did Bard do, from your review of the materials, did Bard do
13 testing that took filters all the way to a failure mode?

14 A. Yes. So they did testing where they took their filters all
15 the way to fracture so the legs or the arms actually broke off
16 in their testing.

02:19PM

17 Q. Is that standard testing to perform?

18 A. Yes. Testing of failure is definitely standard.

19 Q. Did you see any evidence that Dr. McMeeking had offered any
20 suggested alternative test protocols in his analysis?

02:20PM

21 A. He makes some speculation about some changes but doesn't
22 provide any basis or engineering calculations to demonstrate
23 that what he's suggesting would actually be better. And in
24 addition, a lot of the suggestions that are made would have a
25 lot of practical issues in terms of actually being able to

02:20PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct

1 perform the testing.

2 Q. Now, your third opinion related to the Simon Nitinol
3 Filter. Would you tell us what that opinion is again?

4 A. Sure. It is simply that the Simon Nitinol Filter from an
5 engineering perspective is not an alternative design to the
6 Bard filters, and that's because it lacks the retrievability
7 functionality and benefit that the Bard filters have.

02:20PM

8 Q. You have explained to us and the members of the jury what
9 differences in assumptions that you and Dr. McMeeking used in
10 your analysis. But you would agree that the assumptions Dr.
11 McMeeking made resulted in much higher strains imposed on the
12 filters than what you calculated?

02:21PM

13 A. He calculated higher strains, yes.

14 Q. Dr. McMeeking said that the assumptions he used represented
15 worst-case scenario testing. What does worst-case mean in that
16 context in the engineering world?

02:21PM

17 A. Sure. So worst-case analysis talks about understanding the
18 environment of what your product is going to undergo and being
19 able to estimate a foreseeable maximum load, you might say, of
20 what the product is going to see.

02:21PM

21 Q. In your opinion, do Dr. McMeeking's assumptions represent
22 worst-case?

23 A. No. He goes beyond worst-case, as we talked about. He
24 incorporates assumptions and properties for the surrounding
25 tissues in the IVC beyond what the body can actually do. So

02:21PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Direct~~

1 calculating under conditions that are beyond what we know isn't
2 going to happen isn't particularly useful.

3 Q. If Dr. McMeeking were to criticize your assumptions as best
4 case, would you agree with that characterization?

5 A. No. Not at all. We used conservative assumptions all over 02:22PM
6 the place. We had the whole filter we talked about. The
7 tissue properties we used were at three standard deviations
8 above the mean, the average value of what's reported for these
9 properties. So we had conservative assumptions, or
10 conservative inputs, I should say, throughout the analysis. 02:22PM

11 Q. Dr. Briant, other than his computer modeling and his hand
12 calculations, have you seen any other evidence of testing
13 performed by Dr. McMeeking to support his opinions?

14 A. No, I haven't.

15 Q. Thank you. That's all I have. 02:22PM

16 THE COURT: Cross-examination.

17 CROSS-EXAMINATION

18 BY MR. STOLLER:

19 Q. Good afternoon, Dr. Briant.

20 A. Good afternoon. 02:23PM

21 Q. We have not met. My name is Paul Stoller. How are you
22 this afternoon?

23 A. Good. How are you?

24 Q. Good, thank you. I represent Doris Jones. I want to spend
25 some time this afternoon asking you about the testimony you 02:23PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Cross

1 just gave.

2 Let me start with a question about the scope of your
3 assignment. Is it -- am I correct to say that your role in
4 this litigation has been to review the calculations and
5 opinions that Dr. McMeeking has given?

02:23PM

6 A. That has been the majority of my role, yes.

7 Q. I believe you testified at your deposition that you were
8 not asked by Bard or its lawyers to do anything beyond that.
9 Is that fair?

10 A. I have one opinion in my report that talks about the
11 testing that Bard did, but everything else has been focused on
12 Dr. McMeeking.

02:24PM

13 Q. Your opinion with respect to the testing that Bard did was
14 in response to Dr. McMeeking's criticisms. Is that fair?

15 A. By and large, yes.

02:24PM

16 Q. And is it also fair to say that you didn't go back and do a
17 full and comprehensive review and look at everything Bard did
18 to test their IVC filters and come up with opinions as to
19 whether or not that was reasonable and comprehensive?

20 A. That's correct.

02:24PM

21 Q. So let me ask you a couple things. And the starting point
22 when we talked about your testimony is largely about the
23 disagreements with Dr. McMeeking's assumptions and his
24 methodologies. Is that fair?

25 A. That's correct, yes.

02:24PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Cross

1 Q. But you agree with me that Dr. McMeeking is well qualified
2 to provide opinions in the area of mechanical engineering and
3 solid mechanics?

4 A. Dr. McMeeking has a long history of solid mechanics work in
5 this respect in the field, yes.

02:25PM

6 Q. I appreciate your answer. My question was a little bit
7 different. You would agree with me he is a qualified and
8 competent mechanical engineer?

9 A. I would think so, yes.

10 Q. So what we're talking about here is not a difference of you
11 saying he doesn't know what he's talking about, it's a
12 disagreement in terms of the assumptions he applies and the
13 methodologies he uses. Is that fair?

02:25PM

14 A. Correct. My role here was to review the analysis for this
15 case and the calculations and the methodologies that were used
16 for this analysis.

02:25PM

17 Q. And again, I'm going to -- if I ask a yes or no question,
18 do your best to answer yes or no. If you don't understand it
19 or you can't answer it yes or no, just tell me and I will try
20 to ask a better question. Is that fair?

02:25PM

21 A. Sure.

22 Q. So again, the fundamental difference here is one about you
23 disagree with the assumptions he makes and the methodologies he
24 applies. True?

25 A. Correct.

02:26PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Cross

1 Q. And we talked about it's not a matter of qualification,
2 it's also not a matter of you think he made math errors like
3 calculation or computational errors. Is that true?

4 A. That's true.

5 Q. And you have identified for this jury a number of areas
6 that you have disagreement with Dr. McMeeking on his
7 assumptions. True?

02:26PM

8 A. That's correct. There's several areas.

9 Q. One was you disagree with his focus on a single arm versus
10 the whole filter, correct?

02:26PM

11 A. Correct. I think that by incorporating explicitly only a
12 single arm in the analysis it forces you to make a variety of
13 assumptions.

14 Q. Can I cut you off? I just needed a yes or no. We can talk
15 about some of those things, but I want to tick off the list if
16 that's all right. We're coming up to a break so I want to try
17 to move quickly. Is that all right?

02:26PM

18 A. Sure. I get excited.

19 Q. Understood. Happens to me too. We love our science,
20 right?

02:26PM

21 A. Who doesn't?

22 THE COURT: Everybody raise your hand who. . .

23 BY MR. STOLLER:

24 Q. I just want to move through the list, though. The first is
25 single arm versus whole filter, correct?

02:27PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Cross

1 A. Yes. That's correct.

2 Q. And these aren't necessarily in the order you have
3 addressed them, but I want to tick them off.

4 The other is you disagree on the stiffness of the
5 surrounding tissues?

02:27PM

6 A. Correct. Dr. McMeeking assumed those infinitely stiff as
7 opposed to deformable.

8 Q. Let me stop you again. Just yes or no for now, okay?

9 You disagree on stiffness of surrounding tissues.

10 True?

02:27PM

11 A. That's correct.

12 Q. And you disagree not as much on his assumption but a
13 methodology that he chose to apply a linear elastic methodology
14 versus a superelastic methodology. True?

15 A. That is another one.

02:27PM

16 Q. And another one is the -- you disagree about the geometry
17 of the IVC itself and its effect on the filter and vice versa?

18 A. Correct, that the -- he assumed that the IVC would not
19 respond to the presence of the filter.

20 Q. Okay. Again, yes or no if we can.

02:27PM

21 So those are your fundamental disagreements for the
22 most part when you talk about the areas of the difference in
23 fatigue resistance, is that fair? Wait. One more. Difference
24 in terms of the resistance of Nitinol itself, correct?

25 A. Yes.

02:28PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Cross

1 Q. With those -- with that addition, you would agree with me
2 those are the areas of disagreement?

3 A. Yes. As I recall, those are the primary ones.

4 Q. And would you agree with me that in his calculations, and
5 you would -- let me stop for a minute.

02:28PM

6 You know that Dr. McMeeking did both hand calculations
7 and, for a number of things, he did finite element analysis,
8 correct?

9 A. He did both. The majority of his work was hand
10 calculations. And especially for strain, he did some finite
11 element analysis. However, he used the same assumptions in
12 both his FEA as well as his analytical calculations I know.

02:28PM

13 Q. Doctor, Judge Campbell's got me on a play clock. My time
14 becomes valuable. So best you can, yes or no.

15 He did both, though. He did hand calculations and he
16 did finite element analysis?

02:28PM

17 A. He did both, yes.

18 Q. And in both of those situations, in most of them, at any
19 rate, he made the following assumptions about the filter
20 itself; that the filter was tilted, that it was perforated,
21 that it was endothelialized in many instances, and that the IVC
22 surrounding and surrounding organs around the filter were
23 relatively or completely stiff. Is that fair?

02:29PM

24 A. Other than tilted I would agree with that.

25 THE COURT: We're going to break at this point.

02:29PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Cross

1 Ladies and Gentlemen, we'll resume at 2:45.

2 (Recess from 2:29 p.m. until 2:45 p.m.)

3 THE COURT: You may continue, Mr. Stoller.

4 MR. STOLLER: Thank you, Your Honor.

5 BY MR. STOLLER:

02:45PM

6 Q. Welcome back, Doctor.

7 A. Thank you.

8 Q. When we left off, I was asking you about some of the
9 assumptions that Dr. McMeeking had made in forming opinions in
10 this case.

02:45PM

11 You believe, as compared to Dr. McMeeking, that the
12 surrounding tissue, the tissue surrounding the IVC would be
13 stiffer than he does, true?

14 A. I think it would be softer.

15 Q. Softer. Thank you for correcting me. It's Friday
16 afternoon before Memorial Day weekend so I guess I have got
17 that going.

02:46PM

18 All right. So you think the surrounding -- tissues
19 surrounding the IVC would be softer, correct?

20 A. Yes, based on the literature.

02:46PM

21 Q. And you believe -- and again, sir, yes or no. If I need an
22 explanation I will ask. All right?

23 A. Okay.

24 Q. Okay. Thank you.

25 You believe that the Nitinol would be more resistant

02:46PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Cross

1 to fatigue than he does, correct?

2 A. Based on the Bard testing, yes.

3 Q. Okay. And I'm going to ask you again, please answer my
4 question yes or no. If you think you need further explanation
5 or you can't answer it with yes or no, tell me. I just need a
6 yes or no answer. Is that fair?

02:46PM

7 A. Sure.

8 Q. Thank you. All right. And the other thing that you -- one
9 of the other things you believe is that the endothelialization
10 of the filter arms or legs would be less restrictive on its
11 movement than Dr. McMeeking believes. Is that fair?

02:46PM

12 A. I think it could be, yes.

13 Q. Okay. You told the jury, I believe I heard you say, that
14 you do not know why Dr. McMeeking did not use the superelastic
15 qualities of the IVC filter in his calculations. Did I hear
16 that correctly?

02:47PM

17 A. Yes.

18 Q. Have you seen Dr. McMeeking's testimony in this case that
19 was given to this jury?

20 A. Yes, I have.

02:47PM

21 Q. So you didn't recall see seeing anything in there where
22 Dr. McMeeking explained why he didn't use the superelastic
23 qualities in testing in evaluating the fatigue resistance of
24 the Nitinol -- or these filters?

25 A. Can I give a non-yes or no answer?

02:47PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Cross

1 Q. Yes or no. Do you recall one way or the other?

2 A. I recall seeing it, yes.

3 Q. Okay. Thank you. Let me ask you this: Your respective
4 calculations and conclusions are based on the differences in
5 those assumptions and the differences in your methodologies.
6 True?

02:48PM

7 A. That's correct.

8 Q. And those are based on calculations and formulas and
9 methods that you learned in your schooling all the way through
10 getting your Ph.D. in mechanical engineering. True?

02:48PM

11 A. As well as my work at Exponent.

12 Q. Fair enough, so even more. A lot of education and
13 experience after that. True?

14 A. That's correct.

15 Q. And the rest of us in the courtroom, unless we have had
16 that sort of experience, probably aren't going to be able to do
17 our own calculations and decide who is right and who is wrong
18 based on the math. Would you agree with me?

02:48PM

19 A. That's possible.

20 Q. Would you agree with me it's probable?

02:48PM

21 A. Probable, yes.

22 Q. So one of the ways that you look at, and you have testified
23 to the jury, assessing are my calculations and assumptions
24 reasonable as you do bench testing, correct?

25 A. That's one of them, yes.

02:48PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Cross

1 Q. That's one of the ways. Would you agree with me that
2 another one of the ways that you look at whether your
3 assumptions and calculations are reasonable and accurate is you
4 look at how the device performs in the real world?

5 A. One can do that, yes.

02:49PM

6 Q. Yeah. And wouldn't you agree with me that it's important
7 clinical data about how devices perform or fail when they are
8 in people is going to give you good information, or some
9 information, that you can use to evaluate about whether your
10 calculations and your assumptions and your methodologies are
11 correct?

02:49PM

12 A. That's one way that you can look at it, yes.

13 Q. And if you are finding, for example, that your testing
14 indicates your calculations and your FEA and your bench testing
15 is indicating to you that a filter is not likely to fracture,
16 but you are seeing higher than expected rates of fracture in
17 the population of patients who have it, that that would be
18 something you would want to know and take into account,
19 correct?

02:49PM

20 A. That would be something you could look at, yes.

02:49PM

21 Q. And it might suggest to you that your testing and your
22 calculations and your FEA are not accurate. True?

23 A. It's something you would want to look at to evaluate, but
24 yes.

25 Q. So, for example, if you were to run a test to try to

02:50PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Cross

1 understand the fatigue limit or the likeliness of fracture due
2 to fatigue of a device, and you ran it out to 32 or 36 or even
3 100 or 200 million cycles and it didn't fracture and it didn't
4 fail, but then in the field you were experiencing a significant
5 number of fractures, that would suggest to you that maybe your
6 test isn't giving you accurate or adequate information to
7 evaluate the likelihood of fracture in the field, wouldn't it?

02:50PM

8 A. It would be something you would want to go back and review.

9 Q. So one of the ways that those of us who don't know the
10 math, don't know the calculations and don't understand the
11 methodologies and haven't had years of schooling, training, and
12 experience can try to assess which of you between Dr. McMeeking
13 and yourself is more accurate is to look at what happens in the
14 field; are these devices more likely to fracture or less likely
15 to fracture. Would you agree with that?

02:50PM

02:51PM

16 A. That could be one way in addition to the inputs and the
17 motivation for the inputs that were used.

18 Q. Again, I'm focusing on the things the folks in this
19 courtroom can do. We can look at and say is this thing
20 fracturing or tilting or perforating, whatever, more than one
21 or the other you have calculated to help us assess who you
22 think is making more reasonable assumptions. Would you agree
23 with that?

02:51PM

24 A. That's something you could do, as I said, in addition to
25 understanding why we use the inputs that we did.

02:51PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Cross

1 Q. Okay. Sure. But again, you both explained we've got to
2 decide so we can look at what's really happening, right?

3 A. That's one way.

4 Q. Okay. And you are aware sitting here that there have been
5 complications in patients with these filters including the
6 Eclipse, correct?

02:51PM

7 A. I'm aware of that, yes.

8 Q. You know that the filters, there have been incidence of
9 caudal migration, correct?

10 A. I'm aware that caudal migration occurs.

02:52PM

11 Q. You know that tilt occurs?

12 A. I know that tilt occurs.

13 Q. You know that fractures occur?

14 A. Yes. I know that fractures occur.

15 Q. You know that perforations occur?

02:52PM

16 A. Yes. I know that.

17 Q. And is it true, sir, that you have not attempted to
18 determine how many or how often that is happening for any of
19 those complications?

20 A. That is correct.

02:52PM

21 Q. And you have done no analysis, for example, of fracture
22 rate for these filters?

23 A. No. I haven't looked at fracture rates.

24 Q. And you didn't look at things like the clinical studies of
25 them that have been done on these devices to determine what

02:52PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Cross

1 rates of failure or fracture exists in those cases. True?

2 A. Not in detail.

3 Q. So, for example, you haven't reviewed in detail the Asch
4 study. Is that true?

5 A. Correct.

02:52PM

6 Q. And you haven't reviewed in detail the EVEREST study. Is
7 that true?

8 A. That's correct.

9 Q. Is it also true that you haven't seen Bard's internal
10 documents in terms of what Bard knew with respect to the
11 frequency or rate of fractures and other failures of its
12 devices?

02:53PM

13 A. So I have seen tables where it suggests that the fracture
14 rates are less than 1 percent.

15 Q. You have seen some tables but have you seen the internal
16 Bard documents where they are tracking trending determining how
17 often filters are fracturing in an identified patient
18 population, or whether those rates are exceeding their
19 expectations?

02:53PM

20 A. No. I have just seen these summary tables.

02:53PM

21 Q. And has Bard provided you any of its internal documents
22 analyzing adverse events rates or rate of events and how those
23 are occurring?

24 A. I don't recall seeing those, no.

25 Q. Let me see if we can agree on a couple things.

02:53PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Cross

1 Would you agree with me that medical device companies
2 must evaluate and test devices for reasonably foreseeable
3 worst-case scenarios?

4 A. I think it's important for medical device companies to look
5 at the environment and to test and evaluate under foreseeable
6 worst-case conditions, yes.

02:54PM

7 Q. So is the answer to my question yes?

8 A. Yes, it is.

9 Q. Let's stick with yes or no. If you can't, let me know and
10 we'll see if we can do an explanation.

02:54PM

11 Would you agree with me it's important to do that
12 testing and evaluation under reasonably foreseeable worst-case
13 scenario to give predictability as to how the design of the
14 device is going to perform in people?

15 A. I think you should do that to understand its performance,
16 yes.

02:54PM

17 Q. So is the answer to my question yes?

18 A. Yes.

19 Q. And you want to understand whether and how the device might
20 fail in foreseeable worst-case conditions. True?

02:54PM

21 A. I'm sorry. Can you repeat the question?

22 Q. You want to, as an engineer, somebody developing and
23 working on a medical device that's going to be implanted in a
24 person, you want to understand whether and how the device might
25 fail in foreseeable worst-case scenarios in a person.

02:55PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Cross

1 A. Yes, you would want to look at that.

2 Q. And that's important to patient safety. True?

3 A. Yes.

4 Q. And you would -- would you agree with me that in the design
5 and development of medical devices, that patient safety is
6 priority number one?

02:55PM

7 A. Yes. I think that.

8 Q. I'd like to talk a little bit about your work as an expert.

9 I think you testified earlier in response to questions by Mr.

10 North that you have worked at Exponent for 10 years since you
11 graduated and had your doctoral degree true?

02:55PM

12 A. That's correct.

13 Q. And for five of those years you have done expert litigation
14 work for Bard. Is that true?

15 A. Yes. That's about right.

02:55PM

16 Q. And I think you said 40 percent of your time is currently
17 spent as an expert in litigation. Is that true?

18 A. Approximately, yes.

19 Q. And then I think you also said that over that period of
20 time, approximately five years, that you have done outside work
21 for Bard. Bard has paid Exponent \$650,000 approximately?

02:55PM

22 A. That's correct.

23 Q. Is that all time that's been? Is that billed and unbilled
24 or is that just money that's been paid so far and there are
25 still outstanding bills?

02:56PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Cross

1 A. That's basically all of it. We bill monthly so it would
2 just be something from this month.

3 Q. And that \$650,000 plus is for your time plus your team's
4 time and other people working on the matter?

5 A. That's correct.

02:56PM

6 Q. But all of that has been related to the opinions that you
7 have offered in this case. True?

8 A. As well as the previous to the MDL work as well.

9 Q. But it's all with respect to the responses to the opinions
10 of Dr. McMeeking and with respect to the design development and
11 testing of these devices, correct?

02:56PM

12 A. That's correct.

13 Q. You haven't offered any opinions, and I think we talked
14 about this earlier, but you haven't, for those services and
15 that money, offered any opinions that the testing and analysis
16 by Bard of its IVC filters was thorough or accurately done.
17 True?

02:56PM

18 A. I haven't offered that opinion, no.

19 Q. And you have not offered any opinion or performed any
20 in-depth analysis of Bard's testing and FEA of its filters.
21 True?

02:57PM

22 A. Other than the last opinion in my report where the opinion
23 notes that Bard considered the relevant complications during
24 their testing and analysis.

25 Q. My question is a bit different, sir, so if I am not clear

02:57PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Cross

1 let me know. But I think my question was: You have not formed
2 an opinion or performed an in-depth analysis for Bard's testing
3 and finite element analysis of its filters. Is that true?

4 A. That's correct, yes.

5 Q. And you have not focused on testing and analysis Bard did
6 in the design process for its IV filters including the Eclipse,
7 true?

02:57PM

8 A. Correct, other than what I stated before. Yes.

9 Q. You have not formed an opinion or an assessment of the
10 general fatigue resistance of Bard's IVC filters including
11 Eclipse. True?

02:57PM

12 A. I have reviewed the data as noted in my report where I
13 think that it is appropriate to use the testing that Bard did
14 in evaluating and determining a fatigue strength for the wire.

15 Q. Sir, isn't it true that you have testified that you have
16 not done sufficient work to be able to form an opinion or an
17 assessment of the general fatigue resistance of Bard's IVC
18 filters?

02:58PM

19 A. That's correct. The statement I was making earlier was,
20 again, with respect to Dr. McMeeking's assumption. Yes.

02:58PM

21 Q. I want to be very clear. You have not done sufficient work
22 to be able to form an opinion or an assessment of the general
23 fatigue resistance of Bard's IVC filters. True?

24 A. That's correct, yes.

25 Q. You have not performed a root cause analysis of Bard's

02:58PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Cross

1 failures -- or excuse me -- of the failures of Bard's IVC
2 filters. True?

3 A. That's correct, yes.

4 Q. And you cannot say whether Bard's IVC filters are
5 reasonably designed because you have not done the work that
6 would be required to answer that question. True?

02:58PM

7 A. Correct. I don't have an opinion on that.

8 Q. So you cannot say whether the Eclipse has a defective
9 design or not. True?

10 A. That's correct.

02:59PM

11 Q. And you do not have any opinions as to whether or not the
12 fracture rates of Bard's IVC filters, including Eclipse, could
13 have been reduced by a different design or good engineering
14 practices. True?

15 A. That's correct.

02:59PM

16 Q. Now, those are all things you could have done, correct?

17 A. I could have looked into those in more detail.

18 Q. Well, let me ask this: The other 60 percent of what you do
19 that's not being an expert in litigation --

20 A. Uh-huh.

02:59PM

21 Q. Let me ask you a question before that. Is it true that
22 when you are an expert in litigation the vast majority of that
23 is for defendants?

24 A. For my work, yes.

25 Q. The other 60 percent of the time when you are not a

02:59PM

5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Cross

1 litigation expert you are doing these kind of things. True?

2 A. That's correct, yes.

3 Q. And you are certainly qualified and competent to do it.

4 True?

5 A. Correct, yes.

02:59PM

6 Q. But you didn't do it in this case because Bard didn't ask
7 you to?

8 A. That's correct. Yes.

9 Q. I have no further questions. Thank you, Doctor.

10 THE COURT: Redirect?

03:00PM

11 MR. NORTH: Yes, Your Honor.

12 REDIRECT EXAMINATION

13 BY MR. NORTH:

14 Q. Dr. Briant, you were asked a few moments ago by Mr. Stoller
15 whether you had looked at complication rates for Bard filters.

03:00PM

16 Do you recall that?

17 A. Yes.

18 Q. Have you seen any evidence that Dr. McMeeking looked at
19 complication rates for Bard filters?

20 A. I don't recall anything as I sit here.

03:00PM

21 Q. But you have seen some documents in your review in this
22 case that did provide data on Bard fracture rates. Correct?

23 A. That's correct.

24 MR. STOLLER: Leading, Your Honor.

25 THE COURT: I didn't hear what was said.

03:00PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Redirect~~

1 MR. STOLLER: Objection. Leading.

2 THE COURT: Sustained.

3 BY MR. NORTH:

4 Q. Have you seen any data regarding Bard fracture rates?

5 A. I have seen these summary tables that I was talking about.

03:00PM

6 Q. What was the general range that those summaries suggested
7 was the Bard fracture rate?

8 A. They were less than 1 percent.

9 Q. Thank you, Doctor. That's all I have.

10 THE COURT: All right. Thank you. You can step down.

03:01PM

11 THE WITNESS: Thank you.

12 MR. NORTH: Your Honor, at this time we would like
13 to -- oh. I think Ms. Helm will handle this.

14 MS. HELM: Your Honor, at this time we call John
15 DeFord by video. I think the plaintiff had some exhibits to
16 admit.

03:01PM

17 MR. CLARK: Yes, Your Honor. Plaintiff would move to
18 admit Exhibit 1031, subject to redaction.

19 THE COURT: Is that all?

20 MR. CLARK: I'm sorry?

03:01PM

21 THE COURT: Is that all?

22 MR. CLARK: There are two exhibits associated with
23 this. Exhibit 1221 is already in evidence.

24 THE COURT: Any objection to 1023?

25 MS. HELM: None, Your Honor.

03:01PM

~~5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8-Briant-Redirect~~

1 THE COURT: Admitted.

2 MR. HELM: May I approach and read the summary?

3 MR. CLARK: And, Your Honor, we have a conversion
4 chart if it's helpful to the jury.

5 THE COURT: You can just read them.

03:02PM

6 MS. HELM: Deposition Exhibit 294 is Trial Exhibit
7 1221, and Deposition Exhibit 283 is Trial Exhibit 1031.

8 THE COURT: 283?

9 MS. HELM: 283 is 1031.

10 Dr. John DeFord is a senior vice president for science
11 technology and clinical affairs at Bard. In this role, Dr.
12 DeFord is responsible for research and development functions at
13 the various divisions of Bard. Dr. DeFord obtained both
14 Bachelor's and master's degrees in engineering before obtaining
15 his Ph.D. in electrical biomedical engineering in 1990.

03:02PM

16 Prior to joining Bard in 2004, Dr. DeFord held various
17 positions at other medical device manufacturers including
18 serving as the president and chief officer of Cook Medical,
19 Inc.

20 (Video testimony of Dr. John DeFord played in open
21 court.)

03:03PM

22 MS. HELM: Your Honor, at this time the defendants
23 call Mark Wilson also by videotape. There are no exhibits that
24 accompany this deposition.

25 And Mr. Wilson discusses his background and employment

03:34PM

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8—

1 in the deposition, so we'll just let it play.

2 THE COURT: Okay. We're going to take 60 seconds and
3 let everybody stand up first.

4 MS. HELM: Your Honor, may we approach on a very
5 administrative issue, something real simple relating to this
6 video? 03:34PM

7 THE COURT: Yes.

8 (Discussion was had at sidebar out of the hearing of
9 the jury:)

10 MS. HELM: I just wanted to let the Court know that
11 this video is 24 minutes long. So if we can start we can get
12 it in at 4:00 and not have -- 03:35PM

13 THE COURT: We'll go until it's in.

14 MS. HELM: That was all I wanted.

15 (In open court.) 03:35PM

16 THE COURT: We're told, Ladies and Gentlemen, this
17 video is 24 minutes long. We'll watch it to the end but that
18 might run us a few minutes past 4. Better to get it all done.

19 Please be seated. Let's go ahead with the video.

20 (Video testimony of Mark Wilson played in open court.) 03:37PM

21 THE COURT: All right. Ladies and Gentlemen, we are
22 finished for the week. I will plan to see you Tuesday morning
23 at 9. Please remember not to discuss the case or do any
24 research. We hope you have a good weekend. We'll see you on
25 Tuesday. 04:02PM

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8—

1 (Jury out at 4:02 p.m.)

2 THE COURT: How are we allocating the video time?

3 MS. HELM: For the two videos combined, the plaintiffs
4 have a total of 10 minutes.

5 THE COURT: 10 minutes to plaintiffs?

04:02PM

6 MS. HELM: Yes, Your Honor.

7 MR. CLARK: Total.

8 THE COURT: All right. Counsel, give me just one more
9 minute.

10 All right. As of the end of today, plaintiff has used
11 25 hours, 18 minutes. And defendant has used 15 hours, 32
12 minutes.

04:04PM

13 So we're going to talk about jury instructions. Give
14 me just a minute.

15 MS. HELM: Your Honor, can we take a quick break
16 before we start the jury instructions?

04:05PM

17 THE COURT: Yeah. That's fine.

18 MS. HELM: Thank you.

19 (Discussion off the record.)

20 THE COURT: Are we ready, folks?

04:09PM

21 Okay. So I think what I would like to do is go
22 through the instructions one at a time and get your comments.
23 On what you submitted, you did not make any changes until
24 Instruction Number 14. And I think what I included in my
25 proposal was the 1 through 14 you had proposed. So I'm

04:09PM

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8—

1 assuming there's no issue there.

2 MR. CLARK: Your Honor, I apologize. You are correct
3 that we agreed on 1 through 13. In reviewing the Instruction
4 13 in preparation for this afternoon, I did notice that the
5 last sentence talks about, "However, if an act or omission of
6 any person not a party to the suit was the sole proximate cause
7 of an occurrence, then no act or omission of any party could
8 have been a proximate cause."

04:09PM

9 I think that could be confusing in this particular
10 case since there is no non-party fault allocation or argument.

04:10PM

11 MS. HELM: I completely agree, Your Honor.

12 THE COURT: Okay. We'll take out the last sentence in
13 Number 13.

14 Instruction Number 14, the proposed change from
15 plaintiff was to delete the second and third paragraphs from
16 the end which would be on Page 17. I left them in. I left the
17 third from the end in because that's in the Georgia standard
18 instruction. I left the second from the end in because I
19 thought it accurately reflected what was in the *Browning* case.
20 But I'm interested in any comments that plaintiff's counsel has
21 on that or anything else in Instruction Number 14.

04:10PM

04:11PM

22 MR. CLARK: Your Honor, our concern about the second
23 paragraph on what I have as Pages 17 of 34 in Document 11077,
24 is the same one we expressed before. We think that is
25 highlighting FDA compliance or noncompliance. We do recognize

04:11PM

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8—

1 the *Browning* case talks about that, but we think this gets away
2 from the focus of the instruction and into a comment on the
3 evidence. And that would be the third time in this particular
4 instruction that FDA activity or inactivity is mentioned.

5 So while it is accurate, it is a variable highlight on
6 the FDA's role or not having a role in this case.

04:11PM

7 THE COURT: When you say it's the third time, what are
8 you referring to?

9 MR. CLARK: Well, Your Honor, on Page 16 we have the
10 manufacturer's compliance with industry standards or government
11 regulations, which could only be FDA in this particular case,
12 and then the two paragraphs on Page 17.

04:12PM

13 THE COURT: You said this would be the third time. I
14 see one would be Paragraph 13. Is there another?

15 MR. CLARK: Yeah. I apologize, Your Honor. The first
16 full paragraph is the one we have been discussing, and then
17 following that is the one you left in based on the Georgia
18 pattern instruction. So collectively, they would be three
19 references to the FDA.

04:12PM

20 THE COURT: The one you are talking about is a comment
21 on the evidence is the next to last instruction, or next to
22 last paragraph in the instruction. Is that right? The one
23 that starts, "In deciding."

04:12PM

24 MR. CLARK: Yes, Your Honor.

25 THE COURT: Okay. Any comments from defense counsel

04:13PM

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8—

1 on those issues?

2 MR. NORTH: Your Honor, as the attorney who actually
3 tried the *Browning* case and argued that in the Georgia Court of
4 Appeals, I am particularly devoted to that. I do think it is a
5 hornbook principle of Georgia law and is not a comment on the 04:13PM
6 evidence but instead is simply identifying that as a factor,
7 not a determinative factor but just a factor that can be
8 considered. And I don't believe that the other implications
9 about government regulation make that clear like that does. So
10 I do believe it should be left in. 04:14PM

11 THE COURT: Can I hold you responsible for other
12 things in these Georgia instructions? I told Dave Nahmias, who
13 is a friend, that they really need to clean up this area of the
14 law. It is so confusing in so many areas. So I will put some
15 of the blame on you. 04:14PM

16 MS. HELM: We share your pain, Your Honor.

17 THE COURT: Okay. Anything else on Number 14.

18 MR. CLARK: Not for the plaintiff, Your Honor.

19 THE COURT: Number 15 was an instruction on which
20 there were no proposals for change. 04:14PM

21 MR. CLARK: Again, I hate to be maybe overthinking
22 this, but on the paragraph beginning, "There is no single
23 general way," it has language in there that says, "Based on the
24 instruction that I will give you and the evidence received
25 during the trial," I think what's intended there is the 04:15PM

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8—

1 instruction that follows on this particular instruction. But
2 when I read that, it occurred to me that people might consider
3 that there is going to be a further instruction on that.

4 THE COURT: So how about if we just say based on my
5 instructions and the evidence received during the trial.

04:15PM

6 MR. CLARK: That would cure the problem.

7 THE COURT: Any objection?

8 MS. HELM: None, Your Honor.

9 THE COURT: Okay. On Number 16, I added what I think
10 was a defense proposed sentence in the second to last
11 paragraph, the sentence that begins, "In making the
12 determination."

04:15PM

13 I added that after looking not only at the *Ogletree*
14 case that is cited by defendant but also *Banks versus ICI*
15 *Americas* and *Hernandez versus Crown Equipment*. *Hernandez* is a
16 federal district court case from Georgia, but it specifically
17 says for both strict product liability and negligent design
18 defect claims, a risk utility analysis is applied. That seemed
19 to me to pretty clearly be the case.

04:16PM

20 Now, that raises -- there's an area of ambiguity that
21 raises a real question as to whether or not there are two
22 causes of action in Georgia, one for negligent failure to
23 design and one strict liability -- or strict liability design
24 defect. And I have seen some lower court decisions in Georgia
25 that say there aren't two causes of action anymore. There's

04:16PM

04:17PM

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8—

1 only. And I have seen the Georgia Supreme Court say, no,
2 there's two. That's all it says. It doesn't explain why.

3 So I struggle with this as an ambiguous area of the
4 law but it appears clear to me that negligent design defect
5 claims in Georgia are to include the risk/benefit analysis. So
6 that's why I included it. I'm interested in what plaintiff has
7 to say about that.

04:17PM

8 MR. CLARK: Your Honor, I agree that that area is
9 particularly problematic. It does seem to be somewhat
10 confusing that they were highlighting this particular analysis.
11 But my fear in including this in a negligence issue is that
12 that will hone the jury in on particularly the risk/benefit
13 analysis, which they should do. But they also need to look at
14 the broader scope of conduct that is at issue. There's a risk
15 analysis but there's also whether they acted reasonably in
16 terms of the duty of care.

04:17PM

04:17PM

17 So I think that basically says the only inquiry that
18 they need to look at is the risk/benefit analysis and I don't
19 think that is a correct statement of Georgia law.

20 THE COURT: So how would you phrase it?

04:18PM

21 MR. CLARK: I would say among the things you could
22 consider would be a risk/benefit analysis. Or I would add some
23 language in there to reflect other factors could influence
24 whether a manufacturer acted reasonably. And I don't have a
25 particular list of those factors right now because we get into

04:18PM

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8—

1 this sort of slippery slope. But that's the concern is we are
2 highlighting one aspect.

3 THE COURT: What do we do with the language in
4 *Ogletree* which says, "In a negligent design case the risk
5 utility analysis applies to determine whether the manufacturer
6 is liable"?

04:18PM

7 MR. CLARK: It makes sense to talk to the jury about
8 risk and benefit. I mean, that language is there. And the
9 problem we have is that that's focusing them on exclusively
10 that issue. At least that's how I read this instruction. I
11 think that perhaps we could soften it by saying one of the
12 factors you should consider in this would be that. That way
13 we're telling the jury they should look at that but we're not
14 limiting them to that.

04:18PM

15 THE COURT: Comments?

04:19PM

16 MS. HELM: Your Honor, respectively, I don't think
17 putting in "one of the factors you should consider" is in
18 compliance with *Ogletree*, *Banks* or *Hernandez*, because they say
19 it is the factor. I mean, *Ogletree* as you have quoted and as
20 we have quoted in our statement says in a negligent design case
21 the risk utility analysis applies.

04:19PM

22 MR. NORTH: Your Honor, if I could add too, my
23 understanding of Georgia law is there is no distinction as far
24 as the claim itself. And the implications I have always seen
25 in the Georgia court cases are a concern because the defenses

04:19PM

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8—

1 can be different. Comparative fault, for example, is not a
2 defense generally to a strict liability claim traditionally but
3 it is to a negligence claim.

4 Similarly, the statute of repose is an absolute bar to
5 a strict liability claim, but there are exceptions for certain
6 negligent failure to warn claims. So the defenses are
7 different, but I have never seen any decision since *Banks* and
8 *Ogletree* that makes any distinction between the claim itself.

9 MR. CLARK: Then we're back to the problem of there
10 are two distinct causes of action.

11 THE COURT: Agreed.

12 MR. NORTH: Welcome to Georgia.

13 THE COURT: Okay. I understand that point. I want to
14 go back and re-read the cases in light of your comments, Mr.
15 Clark.

16 Anything else on 16?

17 MR. CLARK: Not from the plaintiff, Your Honor.

18 THE COURT: On 17, I adopted the language you all
19 agreed upon. I included what is the fourth paragraph from the
20 end, which says the parties agree that Bard had a duty of
21 reasonable care. The comment from Bard on that was that that
22 repeats what is in Item 1 above, but it doesn't seem to me to
23 repeat it. Item 1 says this is an element. This paragraph
24 says it's not contested.

25 So that's why I thought it was relevant, and this part

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8—

1 is contesting it had a duty to warn.

2 MS. HELM: Your Honor, we don't have any exception to
3 that language.

4 THE COURT: Okay. So I will leave that in.

5 Bard had also asked in the next paragraph that we add 04:21PM
6 a sentence that says, "In making the determination of whether
7 Bard acted reasonably in warning Dr. Avino, you should consider
8 the same factors for strict liability failure to warn about
9 which I previously instructed you."

10 I didn't put that in for two reasons: One was I 04:21PM
11 thought that that's not the way to instruct the jury because
12 there is no list of factors in the previous instruction and
13 it's not telling the jury clearly what they should look back to
14 find. It seems to me if we're going to tell them it's the
15 same, we should make it the same. 04:22PM

16 And secondly, I wrestle with the language that the
17 Georgia courts have used where they say that the two causes of
18 action apply the same duty concepts, or they have the same
19 duty-based elements, or it's the same duty-based negligence
20 analysis. I don't know what that means. So I don't know if 04:22PM
21 the law is identical for the two claims, although I know there
22 are cases that have said they are essentially the same, that
23 the standard instructions don't give us the negligence and the
24 strict liability failure to warn claims.

25 And in light of that uncertainty, as well as what I 04:23PM

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8—

1 thought was a confusing instruction to go back and look at what
2 I told you before, I didn't include it. But I'm happy to hear
3 what defendants wish to say about that.

4 MS. HELM: Yes, Your Honor. There's a recent,
5 actually, federal district court case, *Shelton versus G-A-L-C-O*
6 *International Limited*, and it only has a Westlaw cite which is
7 3597497. It's a Northern District of Georgia case.

04:23PM

8 THE COURT: That doesn't sound like a Westlaw cite.

9 MS. HELM: 2017 WL 3597497.

10 THE COURT: 3597497.

04:23PM

11 MS. HELM: Yes, sir.

12 THE COURT: Okay.

13 MS. HELM: In that case the court held in a products
14 liability case whether or not grounded in strict liability or
15 negligence, a manufacture's duty to warn depends on the
16 foreseeability of the use in question, the type of the danger
17 involved, and the foreseeability of the user's knowledge of the
18 danger. And it cites to *Dietz, D-I-E-T-Z versus Smithkline*
19 *Beecham*, 598 F.3d 812. Again, showing that in product
20 liability cases, Georgia law insists that a plaintiff show the
21 duty to warn the defendant breached the duty in proximate
22 cause. In other words, they treat strict liability and
23 negligence as a separate cause of action but with the same
24 analysis.

04:24PM

04:24PM

25 THE COURT: Is *Dietz* applying Georgia law?

04:24PM

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8—

1 MS. HELM: Yes, Your Honor.

2 THE COURT: What circuit is it?

3 MS. HELM: Eleventh.

4 THE COURT: And what does it cite as the source of
5 those elements?

04:25PM

6 MS. HELM: I will have to pull the case up, Your
7 Honor.

8 THE COURT: We'll do that.

9 MS. HELM: I'm sorry. I'm reading a summary of it.

10 THE COURT: That's okay.

04:25PM

11 MS. HELM: But again, as the Court has recognized, we
12 have a situation under Georgia law where separate causes of
13 action are recognized but the analysis of those separate causes
14 of action have been co-mingled. And, in fact, in many state
15 court cases, there's not a separate charge given for
16 negligence. Only the strict liability charges are given.

04:25PM

17 So we believe that a reference and maybe a more
18 artfully worded reference to the strict liability factors or
19 the strict liability instruction is warranted in the failure to
20 warn.

04:25PM

21 THE COURT: All right.

22 MR. CLARK: Your Honor, I would have to read those
23 cases, but what we are relying on is the long established
24 principle that there are indeed separate causes of action, and
25 what they are proposing essentially merges them. I don't know

04:25PM

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8—

1 what the jury does with that other than basically have the same
2 answer for both. And it seems to me that the negligence count
3 would be broader because you are looking at foreseeability type
4 issues and things and it's a broader scope of conduct. It's
5 not so focused on what they say the device was at the time it
6 left the manufacturer and those types of things.

04:26PM

7 So again, I think it's appropriate to keep the
8 distinction that we see here.

9 THE COURT: Well, let me share a couple of thoughts
10 for you all to chew on that are troubling me.

04:26PM

11 The standard Georgia instruction for strict liability
12 failure to warn, although whoever wrote the instruction they
13 included in the strict liability section but they removed the
14 word "strict liability" from the title of the instruction. And
15 then they put into the strict liability instruction the
16 sentence that is at the bottom of Page 18 in these
17 instructions, which says, "A manufacturer's duty to warn arises
18 when the manufacturer knows or reasonably should know of the
19 danger presented by the use of the product."

04:26PM

20 That's not strict liability. But if it is a correct
21 statement of Georgia law that this non-negligent failure to
22 warn claim includes that requirement, then there is a
23 distinction, arguably, between the two claims. One is the
24 claim that arises when the product is sold if the manufacturer
25 knows or reasonably should know of a danger presented by the

04:27PM

04:27PM

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8—

1 product. When the product is sold, it's unreasonably dangerous
2 because it doesn't include that warning and the manufacturer
3 knows it, and the continuing duty is a continuing duty wherever
4 that product goes to give the warning the manufacturer knew it
5 should have given when it left its hands, whereas the negligent 04:28PM
6 failure to warn can be a claim that arises later, after the
7 product is sold when the manufacturer knows or should know that
8 the product is dangerous.

9 As written in the standard instructions, that
10 distinction would make sense. I haven't seen that. I don't 04:28PM
11 think we have seen that anywhere in the cases. And I don't
12 know what to do with Instruction Number 15, because it's not a
13 true strict liability instruction but it is the instruction in
14 the Georgia standard instructions.

15 So I throw that out for you all to enlighten me on if 04:28PM
16 you have thoughts.

17 MS. HELM: Your Honor, you are acknowledging what this
18 discrepancy and this, what I call, co-mingling of the causes of
19 action in the Georgia charges. I actually think that we have
20 addressed it collectively rather well here with the strict 04:29PM
21 liability charge and the negligence charge with my one
22 exception that I just want to note for the record. And that's
23 the sentence referring to the strict liability standard within
24 the negligence charge.

25 But I recognize the conundrum that our fellow members 04:29PM

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8—

1 of the Georgia Bar have created for us.

2 THE COURT: Well, in the citation, in the standard
3 instructions to the strict liability instruction for this know
4 or should have known is to a negligent failure to warn case.

5 MS. HELM: Yes, Your Honor.

04:29PM

6 MR. NORTH: But, Your Honor, I do think that *Banks*
7 essentially introduced in the concept or into the doctrine of
8 strict liability design that it really is a reasonableness
9 standard. So I'm not sure it's entirely consistent to have a
10 reasonableness standard and strict liability failure to warn
11 because that's the way the Georgia courts have gone.

04:30PM

12 THE COURT: My point is if they go there, there could
13 be a distinction between the claims. One arises when the
14 product is sold the manufacturer knows or should know that
15 there's a danger about which it is not warning. The other can
16 arise later when the manufacturer acquires knowledge that a
17 product that's already out there has a danger it hasn't warned
18 about.

04:30PM

19 MR. NORTH: That's true. It could be one theory. But
20 the problem then is the courts recognize this continuing duty
21 to warn and don't differentiate.

04:30PM

22 THE COURT: Right, but the continuing duty could be a
23 continuing duty to warn people of what you knew when it left
24 your hands. So it's not a duty that arises with a new set of
25 knowledge, it's the duty that once the product is out of your

04:30PM

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8—

1 hands you better warn people or make sure they know of the
2 danger that you knew about when it left your hands.

3 I don't see that in the cases, but that, to me, would
4 seem a logical way to harmonize the negligence instruction and
5 the strict product liability instruction. Not that we would 04:31PM
6 say anything about that, but under that scenario, a jury could
7 look at the facts and say, well, I don't think Bard knew when
8 the filter left its hands that there was a danger. So it's not
9 subject to strict liability. But it learned later and it
10 negligently failed to follow up with a warning. And you could 04:31PM
11 end up with different verdicts on those two cases of action.

12 Anyway, this is just sort of the puzzling we have been
13 doing.

14 MR. NORTH: I would agree if one could define the
15 continuing duty to warn as the Court does. But I'm not sure, 04:31PM
16 like you said, the courts support that.

17 MR. CLARK: Your Honor, that's the distinction I would
18 make is the one you just offered that there could be evidence
19 that is acquired later that would trigger a responsibility at
20 that point to get out there and warn. And we see that in the 04:31PM
21 automotive context and things like that. So it makes some
22 sense.

23 And that's our suggestion is that in the absence of
24 clarity from the case law that we go the direction that the
25 Court has at least preliminarily indicated makes sense. 04:32PM

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8—

1 THE COURT: Well, my intent will be to leave
2 Instruction 15 the way it is because that follows the model
3 instruction from Georgia and that's what everybody seemed to
4 think was okay. I will give further thought to whether we
5 should say something in Instruction 17 that refers back to or 04:32PM
6 repeats some of the instruction from 15 after I read the
7 *Shelton* case. And I will get this again to you probably by the
8 end of Tuesday so that we'll have a chance to talk about it
9 before we charge the jury.

10 Anything else on Instruction 17? 04:32PM

11 MR. CLARK: There is one issue on 17, and the Court
12 has adopted the language we proposed about the parties agree
13 that Bard does have this duty. I think a corresponding change
14 would be in the last paragraph, because it could arguably be
15 confusing to say that basically there's an agreement that there 04:33PM
16 is a duty, but then we tell the jury that the plaintiff needs
17 to establish all four of these elements or that she won't win.
18 And I think we need to make some modification. Perhaps it's
19 just adding a sentence at the end that says you may consider
20 the first element, duty proven, or something to that effect so 04:33PM
21 that there's no confusion about, well, we're not -- they agree
22 about three but we still have to find three or three of the
23 four. So you must consider the first element proven or you
24 shall consider the first element proven. I think that would be
25 the cleanest way to avoid confusion there. 04:33PM

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8—

1 THE COURT: Comments from defense counsel?

2 MS. HELM: Your Honor, I think it's satisfied by the
3 statement that you have already added where the parties agree
4 that the reasonable -- the duty of reasonable care.

5 THE COURT: What if we did this. What did if we took 04:33PM
6 that sentence which is now after the elements, the parties
7 agree, put that at the beginning of the last paragraph and then
8 have the next sentence say: If Mrs. Jones has failed to prove
9 any other element by a preponderance of the evidence. Does
10 that do it? 04:34PM

11 MR. CLARK: That would do it.

12 MS. HELM: That --

13 THE COURT: Okay. On Instruction -- well, there were
14 a couple of related instructions that were proposed. There was
15 a plaintiff's proposal on the instruction regarding a 04:34PM
16 manufacture's scope of knowledge. I understand plaintiff's
17 reason for proposing it. It was proposed in the Booker case.
18 The cases cited, the *Borel* case and the *Mercer* case, are Texas
19 law. I'm not going to give it for the same reason I didn't
20 give it in Booker. I don't think it's part of Georgia law, 04:35PM
21 even though I understand why you proposed it.

22 Similarly, on plaintiff's proposed instruction on the
23 scope of the duty to warn, I elected not to give that because
24 it's not part of the Georgia standard instructions, and I think
25 it's fairly encompassed within the instructions that are going 04:35PM

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8—

1 to be given.

2 Same thing for plaintiff's proposed instruction
3 regarding risks to be warned about. Same thing for defendants'
4 request for an instruction on failure to read the warning. As
5 I concluded in Booker, there's a proximate cause element in
6 both failure to warn claims. Proximate cause is explained in
7 Instruction Number 13. I think it's well covered and defendant
8 can make this argument as the plaintiff can make the other
9 arguments.

04:36PM

10 We took out Instruction 18, which was the instruction
11 about Dr. Amer's negligence. We took out 19 which was about
12 comparative fault. We took out 20 about Dr. Kang. The
13 assumption of the risk defense which is Instruction 18 is the
14 same as you all agreed to.

04:36PM

15 MR. CLARK: Your Honor, may we be heard on that one?

04:36PM

16 THE COURT: Yeah.

17 MR. CLARK: Your Honor, I think the evidence in this
18 case at this juncture would not support an assumption of risk
19 instruction.

20 THE COURT: Key word there is at this juncture. You
21 would be absolutely free to make that argument when we get to
22 the end of the evidence and I will consider it.

04:37PM

23 I did not include the plaintiff's FDA warning
24 instruction for the same reasons I didn't include it in Booker.

25 MR. CLARK: Before you move on, could we be heard on

04:37PM

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8—

1 that?

2 THE COURT: Yes.

3 MR. CLARK: Your Honor, I think it's particularly
4 important in this case to include that instruction, and we did
5 propose a different instruction that I think is hopefully less
6 of a comment on the evidence than what was presented in Booker.
7 But in this particular case there have been a number of
8 references, and I don't suggest that they are intentional, but
9 I think we need to do something about the sort of littered
10 statements about approval in the case.

04:37PM

04:37PM

11 And just a couple of examples from yesterday, Ms.
12 Tillman testified that on Page 1418 of the daily transcript we
13 received, that because the FDA has approved and, dash dash, has
14 cleared the G2 for retrievable indications at this point. Mr.
15 North asked her a question on Page 1442: Did the FDA ever
16 authorize or approve any Bard filters that received the
17 retrievable indication? So we had that, and I don't have a
18 transcript but there were a number of references to approval
19 through Ms. Shari O'Quinn, and I acknowledge there was some
20 effort to try and clean that up by Mr. North. But I don't see
21 this as a comment on the evidence that there's another
22 instruction that will be given talking about the particulars of
23 the FDA that either party can call them as witnesses.

04:38PM

04:38PM

24 So I don't think this would be conspicuous in that
25 way, but it is an explanation and it is a correct statement of

04:38PM

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8—

1 the law. And I just think having that clarity would avoid any
2 potential confusion on that part.

3 THE COURT: Defense counsel?

4 MR. NORTH: Your Honor, I think we have been very
5 careful, obviously just about anybody, I think even some of the 04:39PM
6 plaintiff's experts, have used the word "approval." It's just
7 a failing that people make. We have tried to be very
8 scrupulous in being precise. Dr. Tillman corrected herself
9 yesterday. I made sure that Ms. Allen corrected herself today
10 because she accidentally used the word "approved" a couple of 04:39PM
11 times. I certainly have used the word "clearance" I think in
12 all of my questions. Ms. Allen even explained to the jury why
13 she lapsed and used "approval" because most of her work is with
14 PMA devices.

15 Secondly, I don't think their proposed instruction is 04:39PM
16 an accurate statement of the law. As this Court has held and
17 recognized, while the FDA's 510(k) process does not make an
18 affirmative finding that a device is safe and effective, it
19 does determine whether the device, new device, is as safe and
20 effective as the predicate device. It is a comparative 04:40PM
21 analysis. So for this instruction to say it does not evaluate
22 devices for safety and efficacy is simply not the law.

23 Lastly, I think this is very much a comment on the
24 evidence. The regulatory process has been accurately
25 portrayed, and I don't think that the Court should specifically 04:40PM

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8—

1 wade into comment on this.

2 THE COURT: I'm sensitive to the issue. I'm
3 highlighting in my notes as I go through when something is said
4 that helps one side or the other on this argument. When we get
5 to the end I will consider it again.

04:40PM

6 MR. CLARK: Add it to your notes if it's not already
7 there the testimony of Mr. DeFord today.

8 THE COURT: I noticed that from Mr. DeFord, and I put
9 an asterisk there, too. I'll tell you I have got three places
10 with asterisks where it's been very clearly explained it's
11 clearance not approval. There are some ambiguities,
12 particularly with DeFord where he said, yeah, they say that but
13 they really look at safety and effectiveness. And I will
14 consider all that at the end whether I think there's a risk of
15 confusion for the jury.

04:40PM

04:41PM

16 I did not include defendants' request for instruction
17 on jury deliberation on product defect. I think that's
18 repetitive of what's already in the defective design
19 instructions.

20 On damages, this one I think we need to -- this has
21 general categories of damages. And we have limited, or
22 plaintiff has limited damages claims that are going to be made
23 in order to eliminate some of the health issues that would
24 otherwise be brought in about Ms. Jones. So it seems to me we
25 need to refine the list of Items 1 through 8 in some degree to

04:41PM

04:41PM

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8—

1 reflect the narrowed claim the plaintiff is making. Otherwise
2 we're saying to the jury in this anything is fair game that's
3 within these eight.

4 So my thought is what we ought to have you do is
5 confer, see if you can agree on something that's narrowed on 04:42PM
6 what plaintiff has said at the trial. If you can't, give me
7 your sort of competing proposals about how it should be
8 narrowed. But it seems to me we should be doing some
9 narrowing because there clearly has been a narrowing of the
10 plaintiff's damages claims. I think it's not productive to 04:42PM
11 talk through it now and draft it by committee at 15 to 5 on
12 Friday evening. But why don't you confer about that. And if
13 you can agree, great. If not, give me your proposals and that
14 will at least advance the ball some.

15 MS. HELM: When would you like that, Your Honor? 04:42PM
16 Tuesday?

17 THE COURT: Yeah, if you could get it to us by the end
18 of Tuesday then we can consider it with what I get back to you.

19 MS. HELM: Thank you, Your Honor.

20 THE COURT: I put a question mark after Instruction 04:43PM
21 Number 20, because I didn't know if the evidence would support
22 it. I think that's an issue we can address. This is the
23 failure to mitigate unless plaintiff thinks it's okay. If you
24 think it's not going to be supportive you might want to address
25 that at the end of the evidence. 04:43PM

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8—

1 MR. CLARK: We think it is not yet supported. We can
2 come back later.

3 THE COURT: The form, I think, is the pattern
4 instruction. So I'm assuming form is okay if I conclude it's
5 supported by the evidence. I won't worry about the language
6 and we'll talk about whether it's supported later.

04:43PM

7 The rest of the instructions up to punitive damages
8 is, or are, deliberation instructions. On punitive damages,
9 which is Instruction A on Page 33, Item 4 is the profitability
10 of Bard's wrongdoing, and defendants ask that we include in
11 Georgia. My understanding from reading the cases and Jeff's
12 reading the cases on the same issue, is that the profitability
13 of wrongdoing in a punitive damages award is relevant if the
14 jury is being asked to in effect disgorge profit that the
15 defendant has earned as punishment for their wrongful conduct.

04:44PM

04:45PM

16 If that is the idea behind the profitability of the
17 wrongdoing then it seems to me logically it should be limited
18 to the state of Georgia, although that's not in the standard
19 jury instruction. The standard instruction does say, however,
20 that this element should only be given if it is supported by
21 the evidence. And so I guess the question I have for
22 plaintiff's counsel is, if we get to a punitive damages phase,
23 do you intend to try to present evidence about the
24 profitability of the IVC filter business and argue for some
25 kind of a disgorgement measure of punitive damages?

04:45PM

04:45PM

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8—

1 MR. CLARK: Speaking not necessarily by committee
2 here, I will certainly start the ball rolling on that. We had
3 focused on it more from a constitutional standpoint under the
4 *State Farm* and *Gore* guidepost analysis and did not feel that
5 that was an appropriate measure under that. So I have not
6 given consideration to the disgorgement idea.

04:46PM

7 I do think there has been some evidence in the case
8 concerning profitability in the sense that when we talked to
9 Mr. Baird, at that time Bard had a smaller segment of the
10 market and eventually through his tenure there got itself to
11 the number one position in the market.

04:46PM

12 There is some, or will be some discussion potentially
13 in the monthly management reports concerning profitability.
14 Now, do we have evidence about that specific to Georgia, if
15 that's the focus I'm not aware of that.

04:46PM

16 THE COURT: Let me make another comment so you can
17 factor this in. When you look at Item 6, which is the
18 financial circumstances, the financial condition or net worth
19 of Bard, defendants again proposed we say, based on the sale of
20 Eclipse in Georgia, that to me isn't the right consideration.
21 Item 6 is the how much does it take to make it sting kind of
22 analysis. In fact, some of the case law talks about making it
23 sting.

04:47PM

24 So the notion is how much of an award is necessary to
25 truly be punitive for this entity. That isn't related to what

04:47PM

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8—

1 happens in Georgia. That has to do with one of the resources
2 of this entity and how much will it take to get their
3 attention.

4 So I didn't think we ought to include Georgia in Item
5 6, but the way it was argued by plaintiffs in Booker was not
6 disgorge the profits, it was get the attention of this big
7 corporation. If that's going to be your argument again, seems
8 to me 4 comes out; 6 stays in, and it's not limited to Georgia
9 because it's the what does it take to sting kind of question.

10 MR. STOLLER: Can we put our heads together for just a
11 second? I think we can address that.

12 THE COURT: That's fine.

13 (Discussion off the record.)

14 MR. CLARK: Our recommendation, Your Honor is we
15 strike Item Number 4.

16 THE COURT: Okay. What are defendants' thoughts on
17 these issues?

18 MS. HELM: I think striking Number 4 is appropriate.

19 THE COURT: Okay. Did you want to say anything about
20 6 and my thinking on it?

21 MS. HELM: I respectfully disagree, but I understand
22 the Court's position.

23 THE COURT: Then I will take out 4. We will make
24 Number 5 Number 4 and Number 6 Number 5 and not include Georgia
25 in Number 6, which will become Number 5.

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8—

1 I did not get you a verdict form with these proposals.
2 We haven't had time to look at that or talk about it. But you
3 proposed one that I think was pretty similar to what we used
4 last time that took out Dr. Kang and Dr. Amer.

5 MS. HELM: The defendants proposed one that was very 04:49PM
6 much based on the verdict form you gave in Booker taking out
7 the non-party at fault and the intervening cause. The
8 plaintiffs propose, I think, a one-line verdict form.

9 MR. CLARK: For the same reasons we did in Booker,
10 Your Honor. 04:49PM

11 THE COURT: I don't want to give a one-line for the
12 same reason I didn't in Booker. I will look back to the
13 defendants' proposal but my anticipation is to give essentially
14 the same verdict form with Kang and Amer taken out. But we'll
15 get that to you as well by the end of Tuesday. 04:50PM

16 What else do we need to talk about?

17 MR. NORTH: Your Honor, I just thought I would give
18 the Court a heads up that I think that we are on a very similar
19 schedule from the defense standpoint as last time, probably
20 finishing and concluding our case after lunch on Wednesday. 04:50PM

21 THE COURT: That's fine. In terms of overall time, we
22 are 10 minutes behind schedule, which isn't bad. We can catch
23 up by just going until 4:30 on Tuesday.

24 MR. CLARK: Plaintiffs would be happy to be only 10
25 minutes behind schedule. 04:50PM

—5-25-18-MD 15-2641-Jones v Bard-Jury Trial-Day 8—

1 THE COURT: I understand. My point is I think we're
2 not -- we have been getting five and-a-half hours of trial time
3 a day with the exception of yesterday where we lost a half
4 hour. So I think we're okay on the schedule.

5 Have a good weekend. We'll plan to see you on
6 Tuesday.

04:50PM

7 (Proceeding recessed at 4:51 p.m.)
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

C E R T I F I C A T E

I, LAURIE A. ADAMS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control.

DATED at Phoenix, Arizona, this 26th day of May, 2018.

s/Laurie A. Adams

Laurie A. Adams, RMR, CRR